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CONTAMINATION FROM ETHYLENE DIBROMIDE (EDB)

HEARING

BEFORE THE

SUBCOMMITTEE ON
TOXIC SUBSTANCES AND ENVIRONMENTAL
OVERSIGHT

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

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CONTAMINATION FROM ETHYLENE DIBROMIDE

FRIDAY, JANUARY 27, 1984

U.S. SENATE, COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS, SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT,
Washington, D.C.

The subcommittee met at 9:10 a.m., in room SD-406, Dirksen Senate Office Building, Hon. Dave Durenberger (chairman of the subcommittee) presiding.

Present: Senators Durenberger, Abdnor, and Baucus.

OPENING STATEMENT OF HON. DAVE DURENBERGER, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator **DURENBERGER**. The hearing will come to order. I appreciate everyone's adjusting their schedule. We have called this hearing to examine the contamination of foodstuffs and occupational environments by the toxic pesticide ethylene dibromide, which we will refer to as EDB.

This potent cancer-causing substance has been found in the foods we eat and in many water supplies. Workers have been subjected to cancer risks.

There is a growing realization that somehow the institutions upon which we rely to protect us from the unseen dangers of toxic chemicals may have failed us.

It is easy to get the impression that our problems with EDB have sprung upon us all at once because the public has discovered them only recently. They have not. EDB was first registered as a pesticide in this country in the year 1948. In 1956, our Government said no tolerance levels were necessary for EDB; and today, 28 years later, there still are no tolerance levels for EDB.

For the past 35 years, EDB has been used extensively to fumigate our soils, our stored grain, our milling machinery, citrus fruit, to name only a few uses. At first, using the detection methods available at that time, officials thought that no EDB residues were being left behind. But the sensitivity of the analytical methods increased a thousandfold, and Government officials have known for several years now that there are EDB residues in the food that we eat and in the water many people drink.

After 26 years of EDB use as a pesticide on food, a study finally was performed to see if it can cause cancer. The results of that study said it can. It said that EDB is a potent carcinogen.

The National Cancer Institute issued the first cancer alert on EDB in 1974, 10 years ago. Three years later, in 1977, the National Institute of Occupational Safety and Health, NIOSH, recommended a drastic reduction in the workplace standard. In 1980, the Environmental Protection Agency concluded that the risks of EDB use exceeded its benefits and announced plans to take it off the market. That was over a thousand days ago. But it wasn't until October 1983 when extensive ground water contamination was documented that EPA went ahead with its regulation.

Now, in January 1984, 10 years after the first cancer alert and 6 years after EPA started its regulatory process, we are seeing the first attempts to restrict EDB usage and to determine whether our food is safe. The Government institutions in which we place our trust should have anticipated the problem. Even after it was discovered, the ponderous machinery of Government moved too slowly, even under repeated prodding and legal petitions from labor and environmental groups.

Testimony today will show us that more research and testing and examination has taken place in the last 6 months than in the previous 36 years.

Frustrated by the inability of the Federal Government to take decisive action, and faced with burgeoning environmental and public health concerns, States have begun to move on their own. After finding extensive ground water contamination, Florida banned EDB use as a soil fumigant 2 months before EPA did. California adopted a stricter workplace standard over 2 years before the Federal Occupational Safety and Health Administration even proposed one. Frustrated by the absence of Federal guidance on acceptable food contamination levels, Florida pulled 77 products off the shelves and California closed its borders to EDB-treated Florida oranges.

These are just some of the reasons for a growing lack of confidence. We expect more from our Government, and we have a right to expect more. We shouldn't be faced with a situation in which workers are afraid to handle products treated with federally-approved chemicals. We shouldn't have to wonder about the safety of the foods we eat and the water in our wells.

Unfortunately, the American public today is aroused. People want to know the facts about EDB. That is why this subcommittee held a hearing about ground water contamination by EDB last November, and that is why we are here today. This is only the second hearing on EDB contamination and EPA's pesticide program, and it sure will not be the last.

If the levels of contamination in food products is a genuine public health problem, then we all collectively have to face some hard decisions and we have to work together on an aggressive plan to alleviate the problem. If stored grain is contaminated, then we need a plan to assure the lowest possible level of contamination in finished grain products. If workers in the grain and citrus industries are being exposed to unsafe levels of EDB, then better procedures have to be used.

To get the facts before the public, we will examine the risk from EDB exposure. What is its toxicity? What levels of exposure have occurred? How confident are we of the data we have on both toxicity and exposure?

We will discuss the authorities that are available to deal with the problem. We will examine the health, economic, and trade implications of the various actions that might be taken. We will also examine the alternatives to EDB. What practices are people using as they abandon reliance on EDB? What do we know about the health implications of the alternatives?

With the exception of the conclusion that I have already stated about public confidence in the governmental process, as chairman of this subcommittee I have not come to this hearing with any preconceived or preformed conclusions about what steps we ought to take next. I understand that the Administrator of EPA will be making some of those decisions quite soon. When he does, I expect the record created by this hearing will give many people a better opportunity to formulate opinions about his decision. It should help the American public evaluate the steps that the Government and the food industry are taking to assure the safety of our food supplies.

Let me call our first witness. I will use this as an occasion to remind all of the witnesses that their full statements will be made part of the record, unless there is an objection from a member of the committee to doing so, and that those statements should be read or abbreviated within a 7-minute time limitation.

Senator Baucus should be arriving shortly, I will place his opening statement in the record at this point.

[Senator Baucus' statement follows:]

STATEMENT BY SENATOR MAX BAUCUS
SUBCOMMITTEE ON TOXIC SUBSTANCES
JANUARY 27, 1984
ENVIRONMENTAL OVERSIGHT HEARING ON ETHYLENE DIBROMIDE

MR. CHAIRMAN, LET ME COMMEND YOU FOR CONVENING THIS HEARING ON EDB. ACCUSATIONS ARE FLYING ON ALL SIDES. WE NEED TO GET THE FACTS. I WOULD ALSO THANK THE WITNESSES FOR COMING HERE TODAY TO HELP US GET THOSE FACTS.

CHEMICALS PLAY AN IMPORTANT ROLE IN MODERN DAY AGRICULTURE. BUT, WE MUST CONSTANTLY BE ON THE LOOK OUT TO ENSURE THAT THESE CHEMICALS ARE NOT PRESENTING AN UNACCEPTABLE RISK TO THE PEOPLE OF THIS COUNTRY.

THE ENVIRONMENTAL PROTECTION AGENCY FIRST BECAME AWARE THAT EDB WAS A POTENT ANIMAL CARCINOGEN OVER TEN YEARS AGO. THIS BODY OF RESEARCH AND DATA STEADILY GREW, UNTIL THREE YEARS AGO, EPA STATED AT A MEETING WITH OSHA OFFICIALS THAT THEY PLANNED TO TAKE IMMEDIATE STEPS TO BAN THE USE OF EDB. THE ENVIRONMENTAL PROTECTION AGENCY HAD DETERMINED THAT EDB WAS THE MOST TOXIC CHEMICAL THEY HAD EVER EVALUATED. THREE YEARS PASSED, AND NOTHING HAPPENED. IF EPA HAD ACTED THEN, WE COULD ALREADY BE USING ACCEPTABLE ALTERNATIVES.

NOW, SUDDENLY, EPA'S BUREAUCRATIC BUNGLING AND BUCK-PASSING HAS CAUSED A PUBLIC OUTCRY WHICH THREATENS OUR GRAIN AND CITRUS FRUIT INDUSTRY, CAUSES IRRATIONAL ACTIONS BY INDIVIDUAL STATES, AND CASTS A CLOUD OF DOUBT OVER THE USE OF ALL CHEMICALS.

I WANT TO FIND OUT TODAY WHY EPA FAILED TO ACT WHEN ITS OWN DATA DICTATED THAT IT DO OTHERWISE.

I ALSO HOPE TO ADD SOME SEMBLANCE OF RATIONALITY TO THE WHOLE DEBATE. NINETY PERCENT OF THE EDB USED IN THIS COUNTRY IS USED AS AN ADDITIVE IN GASOLINE. NO ONE HAS EVEN RAISED A CONCERN ABOUT THIS USE. AS RECENTLY AS THREE WEEKS AGO, CALIFORNIA TESTED CITRUS FRUIT AND FOUND LEVELS OF EDB AS HIGH AS 16,000 PARTS PER BILLION.

YET MOST PUBLIC ATTENTION HAS BEEN FOCUSED ON EDB IN GRAIN PRODUCTS. THIS ATTENTION HAS FOCUSED ON CONCENTRATIONS AS LOW AS 1 PART PER BILLION. THE MILLING INDUSTRY HAS LARGELY SHIFTED TO ALTERNATIVE MEANS OF FUMIGATION. I AM SURE FARMERS AND GRAIN HANDLERS WILL SHORTLY FOLLOW IN THIS PATH.

LET ME SPEAK FOR A MOMENT ABOUT GRAIN FUMIGATION. I HOPE THAT TODAY'S HEARINGS WILL ANSWER A NUMBER OF QUESTIONS THAT I HAVE CONCERNING THIS ISSUE.

HOW MUCH GRAIN IN STORAGE HAS ACTUALLY BEEN FUMIGATED? ESTIMATES THAT I HAVE SEEN RANGE AS LOW AS 2 PERCENT OF ALL GRAIN, A SMALL AMOUNT WHEN YOU CONSIDER IT IS MIXED WITH UNFUMIGATED GRAIN. I THINK WE ALSO NEED TO REFLECT A MOMENT ON THE CONCENTRATIONS OF EDB THAT HAVE BEEN UTILIZED FOR GRAIN FUMIGATION. IT IS MY UNDERSTANDING THAT GRAIN FUMIGATION IS ACCOMPLISHED WITH A 20 PERCENT PESTICIDE SOLUTION OF WHICH EDB IS ONLY A SMALL FRACTION.

GRAIN HAS BECOME THE WHIPPING BOY OF THE EDB CONTROVERSY. OTHER USES RANGE FROM 80 TO 100 PERCENT EDB.

WE NEED TO IMMEDIATELY GET TO THE BOTTOM OF THE WHOLE DEBATE CONCERNING EDB. EDB IS A POTENT CHEMICAL. THE AMERICAN PUBLIC IS ENTITLED TO KNOW WHETHER OR NOT THEIR FOOD IS SAFE. THOSE WHO PROCESS IT ARE ENTITLED TO KNOW ABOUT THE SAFETY OF THE CHEMICALS THEY ARE HANDLING. THOSE WHO PRODUCE THE FOOD, AMERICA'S FARMERS, ARE ENTITLED TO A SAFE, EFFECTIVE AND ECONOMICAL MEANS OF PROTECTING THEIR HARVEST. EPA NEEDS TO ACT.

Senator **Durenberger.** Our first witness will be Mr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, the U.S. Environmental Protection Agency.

Jack, we welcome you. We appreciate your being here today and look forward to your testimony.

STATEMENT OF JOHN A. MOORE, ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Mr. **Moore.** Good morning. I will give an abbreviation of my full statement, trying to be consistent with your request for time constraints. I would like to briefly review the background of the agency's basic position on EDB which led to the regulatory decisions that were announced last September.

EDB has been used as a pesticide for over 35 years and has been effective in destroying insects in soil, grain, and citrus. As new data on EDB's potential health effects have become available and as alternatives for most major uses have been developed, the balance between risks and benefits has shifted. Based on these new health effects and economic benefits data, the aqency concluded that the risks of continued use outweigh the benefits and, consequently, that registrations for major uses of EDB should be cancelled.

For the soil fumigation use, EPA took the strongest action possible under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], an emergency suspension which immediately halted sale and distribution of EDB products for that use. This action was based on data showing that use of EDB had caused ground water contamination in several States. Soil fumigation accounted for about 90 percent of the use of EDB as a pesticide. For post-harvest fumigation of citrus and tropical fruits, EPA issued a notice of intent to cancel this use of EDB to become effective September 1, 1984. For fumigation of stored grain and the spot fumigation of grain milling machinery, the agency issued a notice of intent to cancel this use effective in 30 days from the time of the announcement.

However, registrants and other interested parties appealed these cancellation notices for the nonsuspended uses—that is, fumigation of citrus, tropical fruit and grain. These nonsuspended uses continue, as permitted by statute, during cancellation proceedings.

The September cancellation notices for stored grain and spot fumigation pointed out that more monitoring data were needed to assess accurately the extent to which EDB residues occur in grain and grain-based foods. To assist the EPA, the Food and Drug Administration as well as the U.S. Department of Agriculture did conduct further monitoring of various foods to clarify this issue.

FDA's 10 regional offices collected 42 samples of milk, bread, baby food, and flour. Except for four wheat flour samples, EDB was not detected. FDA also analyzed 69 samples of stored and processed grain from seven facilities known to have used EDB. A majority of these samples did have detectable levels of EDB.

USDA provided an analysis of meat samples. These data suggest that EDB residues in livestock and poultry are not a significant source of human exposure.

Additional data on EDB residues were collected by a number of States. The State of Florida provided analyses of grain-based food products such as flour, cornmeal and cake mixes taken from store shelves. These findings show detectable residues in roughly one-third of several hundred samples. The majority of positive samples indicate residues from two to forty parts per billion. Similar information has been provided by Texas, Georgia, and North Carolina which generally confirms Florida's findings. At least 16 additional states have informed EPA that they intend to conduct their own sampling of food products for EDB residues.

The agency has been particularly interested in obtaining additional data on the effects of cooking consumer products to determine the extent to which cooking reduces EDB residue levels. I believe you will hear testimony later today qiving specific details of this. It suggests that about an 80-percent reduction in the residues of EDB levels is a function of the final process of cooking. This work has been done by the EPA, FDA, Grocery Manufacturer's Association, as well as some of the States.

In short, EPA is now in the process of collecting the information necessary to clarify the EDB situation. We will then consider three specific actions: First, whether to issue emergency suspension notices, in addition to the cancellation notices already in place, for the uses remaining in effect; second, recommending what residue levels are acceptable in the food supply; and third, removing impediments to Federal enforcement actions by revoking the existing tolerance exemption.

We believe that EPA does have adequate authority to deal with the EDB situation and is currently exercising that authority in a responsible manner. Our responsibility is to assess accurately the magnitude of the risk posed by EDB residues in foods so that the agency can adequately protect public health, without an unnecessary disruption of major portions of the Nation's food supply. While prompt action is necessary to prevent public apprehension, we will only act based on knowledge.

The best procedure is to be used to quantify the risk that is posed to man. In my opinion, in this instance, such a discussion is a peripheral issue since all of these uses pose an unacceptable risk and, therefore, we need to get EDB out of our Nation's food products.

Based on our now larger and more complete data base, the agency is in the process of recalculating the risks of exposure to EDB. Moreover, since EPA's September order already proposed a cancellation of the remaining food uses of EDB, the agency is evaluating the additional risk associated with dietary exposure that is likely to occur if EDB use continues during the cancellation hearings, typically a 2-year process.

It should be understood that if EPA suspended the grain uses of EDB today, many treated commodities would remain in the channels of trade for a considerable time. However, we believe there are certain agricultural practices and manufacturing processes which can reduce residues in treated grain.

Alternatives are available for spot fumigation, and the grain milling industry reports a significant decline in the use of EDB for this use. There are also registered alternative fumigants available for stored grain fumigation. Alternatives for EDB fumigation of citrus and tropical fruits, such as irradiation and cold treatment, are being pursued, although they are not yet generally available on a commercial scale.

In conclusion, EPA believes that the appropriate long-term solution for EDB is to eliminate public exposure by ending the pesticidal uses of the chemical, and regulatory actions were initiated in September 1983 to do just that. The Agency is now gathering the information needed to assess current levels of public exposure and to determine what actions are appropriate to ensure that public health is protected during the time needed to eliminate the use of EDB and its residues from the food supply.

That concludes my opening remarks.

Senator **Durenberger**. Thank you very much.

For the record, would you please describe briefly the results of the Agency's quantitative cancer-risk assessments for lifetime average dietary exposure for EDB ground water contamination?

Mr. **Moore**. As you will recall, it was the presence of EDB in ground water that led to the action of the emergency suspension of its use of direct injection in soil. The figures, as I recall, are such that at a level of somewhere around a tenth of a part per billion you end up with a risk that is roughly equivalent to that risk associated with levels that are found in the Nation's grain supply today.

Senator **Durenberger**. Why don't I ask you to give us those figures exactly for the record.

Mr. **Moore**. Fine.

Senator **Durenberger**. I am informed we don't have them.

[The information requested follows:]

Below is a table giving the quantitative cancer risk assessment for lifetime dietary exposure for various levels of EDB in drinking water.

Ground Water Cancer Risk

The detection limits for EDB vary in different laboratories between 0.02 parts per billion (ppb) and 0.10 ppb. Therefore, the Agency has included these detection limits below, in addition to other observed contamination levels.

Cancer Risks for EDB Ground Water Contamination

Concentration	Lifetime Cancer Risk*
0.02 ppb	3×10^{-5}
0.1 ppb	1.5×10^{-4}
1.0 ppb	1.5×10^{-3}
5.0	7.5×10^{-3}
100 ppb	1.5×10^{-1}

* EPA assumes consumption of 2 liters of water per day for an adult, a 60 kg lifetime average weight, and a 70 year lifetime. This 2 liter assumption includes water consumed per se, as well as water used in reconstituting powdered drinks, etc. Cancer risks, as presented in this table, are the additional risks estimated for a lifetime of exposure.

Senator **Durenberger**. How do these contamination levels compare with actual EDB levels found in contaminated wells? Could you give us that information for the record also?

Mr. **Moore**. Yes; I can give it for the record.

[The information requested follows:]

Below is a table showing the typical levels of EDB found in those states reporting ground water contamination.

States	No. of Counties	No. of Positives (approx.)	Typical Positives (ppb)
California	5	18	0.1-2.0
Florida	9	86	1.0-15.0
Georgia	1	6	0.1-10.0
Hawaii	1	4	0.02-0.1
Total	16	114	0.05 - 5.0

Senator **Durenberger**. I think we would also like information on citrus fumigation workers, grain mill workers, and the like.

Mr. **Moore**. Senator, in a general sense, the greatest risk, without quoting the numbers, is associated with the occupational people involved in the occupational exposure to EDB, followed then by its presence in food products.

The other point I think that is important to make in this regard is some of the data that were in the document that led to cancellation and suspension was based on lifetime risk, which was appropriate at the time one was deciding whether or not one should allow continued use. To the degree we have suspended use or have announced cancellation, it is inferring that there is a finite period of exposure and, therefore, we should be looking at the consequence of that exposure rather than another 70 years of exposure, for example, for a new pesticide.

Senator **Durenberger**. On page 6 of your testimony you state, "EPA is moving expeditiously to revoke the current tolerance exemption for EDB." Could you give us some idea of when you take into account appeals or potential appeals and so forth how long this process of revocation, if it were recommended, might take?

Mr. **Moore**. The nature of the process is such, depending on whether some one objects to the proposal to revoke, it could take a number of months rather than weeks.

Senator **Durenberger**. Could it take a series of years?

Mr. **Moore**. Possibly.

Senator **Durenberger**. When we were here in November, we talked about some of the problems with these time lines. Might it take as long as 3 years for the process to take effect?

Mr. **Moore**. I am told it could extend that way if one availed themselves of all the appeal processes that are associated with such action.

Senator **Durenberger**. On page 7 of your testimony you explained that the reason you cancelled the grain and citrus uses instead of suspending them is that during the appeal period the risks are not unreasonable. If this pesticide is a potent carcinogen, how can you tell consumers that because there has been such a delay until now another 2 years isn't going to make any difference?

Mr. **Moore**. This is why we are currently revisiting the issue, Senator. At the time we made our announcement in September, we did express great concern about the dietary risk that might be associated with its presence in grain products, but that we had a very modest amount of data; and, indeed, stated we would revisit this issue as a function of receiving more data. These data have come in since September and, indeed, we are in the process of revisiting it and considering whether suspension would be a more appropriate action, considering the fact that people did file notice of appeal to the cancellation beyond the 30-day period.

Senator **Durenberger**. I am also interested, again for the record, to know what precisely happened at EPA on the subject of EDB from 1980, when something called Position Document No. 3 indicated the presumption against registration had not been effectively rebutted, and then September 1983 when apparently, because of ground water contamination, as you pointed out, EPA decided to take action. Is there a file at your agency that contains all of the relevant documents on who said what to whom, who might have called or visited from some other agency, that sort of thing? Have you, yourself, made any attempt to find out what happened? Would you care to give us a characterization of what you think happened?

Mr. **Moore**. Senator, I have not availed myself of the opportunity to try to figure out what happened between 1980 and September 1983. I basically focused from September 1983 to the present, given that additional action is needed relative to setting tolerance levels or revisiting whether it should advance the cancellation actions to suspensions. Whatever records are available, certainly they are available to you or anybody else. I don't know what is there as far as a record of who visited or what happened. I will be glad to look into it.

Senator **Durenberger**. What can you tell us about the potential for human exposure to EDB in its use as a gasoline additive, since that is where about 90 percent of it goes, I understand. Your agency apparently has evidence which shows no concern from auto emissions. But you have testified here in the past about gasoline vapors and leaky underground storage tanks. Just what is the situation as you understand it on human exposure?

Mr. **Moore**. There was some concern when the initial ground water levels were detected that indeed it might be attributable to its pesticide use or due to maybe a leaky tank of some sort with a petroleum product, in which EDB is an additive.

The evidence that we have suggests that in all of those instances it is more likely that it was indeed due to a pesticidal use as opposed to a leaking tank of some sort or another.

You are correct that about 90 percent of the EDB utilized in this country is in leaded gasoline. It is not in unleaded gasoline. So to the degree we are reducing the amount of leaded gasoline in this country, we are in the process of eliminating EDB from that source as well. I have seen some data that were put together by the air program which says that the risks that might be associated with

EDB from that source are equivalent to or even a little less than that seen with benzene.

Senator DURENBERGER. Do you want to tell us what that means? I turned to the chemist to see if he understood what you meant. Should we be worried about benzene?

Mr. MOORE. Compared to other things associated with petroleum products, no, it poses no great risk. Now petroleum products are associated with hazards. In the context of what else you are being exposed to at the time you are being exposed to petroleum products, the additional presence of EDB in there doesn't add any tremendous burden to the inherent risk associated with petroleum per se.

Senator DURENBERGER. Grain and citrus industry officials have informed us that they are beginning to use methyl bromide and aluminum phosphate as substitutes for EDB. What information does the agency have about the toxicity of those substances?

Mr. MOORE. I am told that aluminum phosphide was reviewed within the last couple of years, and the data are fairly current on that as opposed to some of the older pesticides. It does have acute toxicity potential, which led to the agency putting it on its restricted pesticide list, so that the average consumer can't get it. You must be licensed to use that product. Its toxicity is primarily an acute toxicity, that is, if you have exposure, you have dire consequences within a matter of a few days or hours as opposed to long-term consequences as we are talking about here with EDB. Methyl bromide is a product that has been around for a long time. It also is known to be associated with acute toxicity. Some of the early evidence suggests that it is also a compound that can cause genetic damage. The nature of the damage that it causes in these genetic test systems leads some people to predict indeed that it may well pose carcinogenic risks. Studies that will define whether or not it is a carcinogen in animals are in progress.

Senator DURENBERGER. In progress?

Mr. MOORE. There are some inhalation studies in progress, early studies by the national toxicology program. I am aware there are studies being conducted in Holland that I think are farther along than the U.S. studies as far as chronic studies.

Senator DURENBERGER. Does EPA have data to show there will be no methyl bromide residues in food if it becomes widely used? Are there any data on this available?

Mr. MOORE. There is not a lot of data dealing with residues of methyl bromide, but I think it would be presumptuous to predict there would be no residues from the use of methyl bromide as a fumigant.

Senator DURENBERGER. Like EDB, methyl bromide is applied to stored grain in combination with carbon tetrachloride; is that not correct?

Mr. MOORE. It can be. I understand carbon tetrachloride's primary use is in combination with carbon disulfide and, until recently, minor amounts of methyl bromide. Methyl bromide is sometimes used by itself.

Senator DURENBERGER. I wonder if you would describe briefly the toxicity of carbon tetrachloride.

Mr. MOORE. Carbon tetrachloride has been probably the chemical that has been studied more by toxicologists than anything I can think of. I believe it is in the RPAR process within the pesticide program. There are again some concerns with toxicity and possibly some long-term carcinogenic potential.

Senator **Durenberger**. Can you describe for us, as best you can, all the options available to the Administrator of EPA to reduce EDB residues in food? Think about that for a second, because I would like you to go through each item—that is, tolerances, suspensions, action levels—and tell us what you could do, what other agencies would have to do, and what the effect on that would be on farmers, on food producers, sellers of various kinds, and then on the consumer.

Mr. **Moore**. Addressing its grain uses its use as a fumigant for grain, one can revisit the issue as to whether or not one may wish to make a pronouncement of suspension of its use. That still permits an adjudicatory process for somebody to appeal its continued use or its continued registration. However, during the process of discussing whether its use should be allowed to continue, you may not use it. That is the clear distinction between a suspension action as opposed to the cancellation action which was announced in September. Had nobody appealed that cancellation action in September, its use for fumigation of spot milling would have ceased within 30 days.

So indeed, the benefit to be gained or to be considered in taking suspension versus the cancellation which has been appealed is that the process typically takes 2 years, or thereabouts, and you are eliminating it from the Nation's grain supply and, by inference, from the food products derived therefrom 2 years sooner.

We obviously can identify guidelines, if you will, or identify numbers that should be acceptable while the Nation's grain supply in this case naturally purges itself from contamination of residue levels. We cannot set such things today and have them legally enforced by the Federal Government immediately because of the exemption status that was imposed back in 1956.

Senator **Durenberger**. That is the exemption status for grain?

Mr. **Moore**. Right.

Senator **Durenberger**. The tolerance level?

Mr. **Moore**. Right. We must go to formal rulemaking to revoke the current exemption.

Senator **Durenberger**. As you are explaining this to us, because we are all trying to get this as a framework, to sort of clarify it, if you would say when you say "we" who you are talking about. If you say we in the EPA context, or you might be saying we in the Federal Government context. I think it would be helpful to all of us to understand where some other agency is involved.

Mr. **Moore**. Any action we are taking say toward revocation of existing exemptions is done in consultation with the Food and Drug Administration. It is my understanding, however, that EPA can propose the formal action in that regard. Once that process has gone through and there is no longer an exemption, one can then propose a level, if you will, for EDB or for any other bromine-containing product. There is an opportunity during that period of time for a public comment period before it can go into effect. As I remember, it is 60 days' public comment period.

We recommend a level. FDA sets that level. FDA will publish that level in the Federal Register as soon as practical, inviting public comment. It can be petitioned during that period of time by an interested party to set a different level than the one that is being proposed. Then using the Administrative Procedures Act we can set a different level by going to a district court challenge, or somebody who disagrees with that level can go to district court to get a different level.

Senator DURENBERGER. Is that one of those 1-, 2-, 3-year processes?

Mr. MOORE. In this example, the tolerance is in place. It remains in place while the challenge process is ongoing. If the challenge is sustained, then it is removed. That deals with action levels, which is likely what would be the more prudent thing to consider in relation to grain.

So the more likely thing that is going to happen, Senator, as far as coming up with a level or a recommendation of a level, given that the problems we have with the current exemption in place are the need to remove that and then to go into the formal process of recommending an action level, is going to take some considerable period of time. It is hoped indeed that such levels as we would identify would be reviewed by the States and the States would consider using those levels within their own jurisdictions. Indeed, we have been asked, or urged, by a number of States to issue such guidance.

Senator DURENBERGER. That probably didn't, because you are doing this off the top of your head, and I appreciate your effort, cover all the bases in that question. But let me ask an additional question. Can somebody in the Government stop you somewhere in this process, just sort of shut it down? Does the Department of Agriculture, for example, have some authority in this chain? I am leaving aside private parties where their rights have to be protected. But is there anybody in Government that can sort of shut this process down at some place because they are a key link in moving to a resolution of this process?

Mr. MOORE. I am not aware of it. Not in this process.

Senator DURENBERGER. Can EPA or the FDA require close monitoring of grain or citrus products? I am getting off the technicalities of this determination process. I am just trying to get on another item.

Mr. MOORE. Can it require somebody, a private party, so to speak, to monitor?

Senator DURENBERGER. Right.

Mr. MOORE. I don't believe they have any legal authority. They might be able to do it out of moral persuasion or something like that.

Senator DURENBERGER. You are not aware of any authority in that.

I am going to have to turn to my colleague here. Before I do, I want to put in the record at this point an excellent article which appeared in the most recent issue of Science magazine which does a very good job of laying out the history of EDB regulation. One item in that article caught my eye. It was also reported in last Saturday's Washington Post. That is that apparently the U.S. Department of Agriculture has formally intervened, along with various private companies, to block EPA's attempts to cancel EDB uses. I suppose I will ask the next witness that question, but has Agriculture also interfered with your efforts in internal administration channels of any kind?

Mr. MOORE. No. In the formal process leading to consideration of cancellation and, indeed, cancellation or suspension, USDA I believe by statute is required to be given the opportunity to comment on products, proposed actions along the way, just the same as there is an outside group, the Science Advisory Panel, which also must review and comment on such actions. For example, it did review the emergency suspension action that was issued in September, the Science Advisory Panel did, and indeed, the action was appropriate in their opinion. We are not bound by the comments of either one, to my knowledge.

[The article referred to by Senator Durenberger follows:]

EDB Contamination Kindles Federal Action

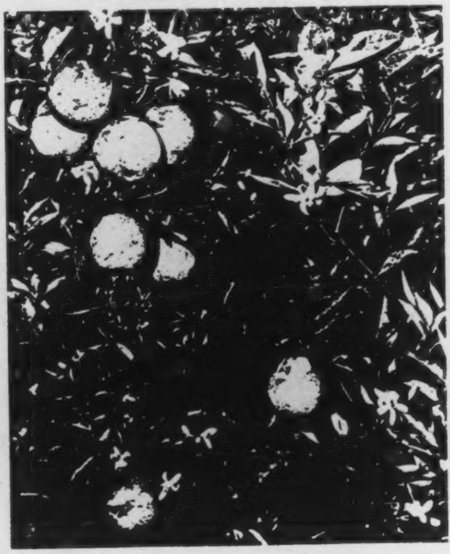
After 7 years, the Environmental Protection Agency finally proposes a complete phaseout of the pesticide, but that upsets USDA

Florida's recent action in banning the sale of more than 70 grain products contaminated with the pesticide ethylene dibromide (EDB) has brought to the boil an issue that has been simmering on the back burners of federal regulatory agencies for 7 years. The Environmental Protection Agency (EPA) first moved to control uses of EDB in 1977, but protests from manufacturers and users and lack of attention during the first 2½ years of the Reagan Administration have so far thwarted federal action.

Florida decided to take matters into its own hands and pulled off grocer's shelves a variety of nationally marketed grain products under brand names such as Betty Crocker, Aunt Jemima, and Pillsbury. Other states have since found EDB-tainted products in their territories, which has sent EPA scrambling to determine what levels of the pesticide should be permitted in food. Farmers and food manufacturers, fearing that the agency could declare a large portion of the nation's grain supply inedible, have called on Secretary of Agriculture John Block to press their case with EPA administrator William Ruckelshaus.

EDB is a popular pesticide because it is effective and versatile. For the past 40 years, farmers have applied EDB to control insect infestation in stored grain. For 20 years, many grain companies have fumigated milling machinery with the chemical. More recently, use of the pesticide has broadened. Farmers in the Southeast and Southwest have injected EDB into soil to kill nematodes before planting crops. During the 1981 medfly crisis, California fumigated fruit grown in-state with EDB and subsequently required imported fruit—primarily that shipped from Florida and Texas—to undergo EDB fumigation. Florida and other states also fumigate citrus fruit shipped to Japan.

State and federal officials now realize that EDB's extensive use has led to a widespread problem. A significant portion of the country's processed grain products may have some contamination, according to EPA's expert on the pesticide, Richard Johnson. So far, he says, 30 percent of the packaged grain products tested by various sources show contamination. (Preliminary studies by Florida indicate that cooking may dissipate about 80 percent of the pesticide, but more experiments are being conducted.)


Florida Division of Tourism

In the late 1970's, researchers discovered that EDB doesn't dissipate in food as previously assumed. Pesticide residues can persist in fumigated citrus fruit for several days and in grain for months.

Last summer California, Florida, Hawaii, and Georgia discovered that ground water in various areas was polluted with EDB from soil fumigation. Most recently, California announced that Florida citrus shipped to the state had worrisome EDB concentrations in the pulp.

The danger to humans from low-level, long-term exposure is not yet clear because no reliable epidemiological studies are available. But according to EPA documents, animal studies demonstrate that EDB is highly toxic. Experiments show that the chemical causes cancer, gene mutations, and reproductive damage in a variety of animal species. Studies by federal agencies in the 1970's indicated that the pesticide is carcinogenic in rats and mice at 20,000 parts per billion (ppb). If EDB were a new chemical, it would never pass muster with current environmental law, according to several federal environmental officials.

Given the animal data and the recent reports of contamination in water and food, EPA officials are now trying to decide whether the agency should issue stricter regulations by declaring an immediate end to all uses of the pesticide. In September, it banned the sale and distribution of EDB as a soil fumigant and said it wants a phaseout of other uses over the next year. The phaseout, however, has been appealed by members of the agricultural community, the chemical industry, and the U.S. Department of Agriculture (USDA). This could delay full cancellation of all EDB use until 1986. EPA's task is also complicated by the fact that the Reagan Administration's Caribbean Basin initiative promotes the importation of tropical fruit from Caribbean countries. USDA import regulations cannot be met without use of the pesticide. The U.S. Agency for International Development, at the urging of USDA, is currently deciding whether it too should appeal EPA's action.

EPA officials are also working feverishly to determine what concentration of the pesticide should be allowed in food because currently there is no federal tolerance standard for EDB. Florida officials, without waiting for federal guidance, concluded that 1 ppb is unacceptable. The 76 products that were banned contained an average range of 15 to 20 ppb of the pesticide, but one food sample went as high as 755 ppb. The Grocery

Manufacturers of America, a national trade group, is fighting the ban tooth and nail but so far has been unsuccessful in obtaining a federal injunction. EPA is expected to announce a standard within the next month.

Regulatory action on EDB has been impeded by two factors. When EPA suspects that a pesticide poses an unacceptable health hazard, federal law requires it to develop regulatory proposals by weighing the risks and benefits and then seeking public comment. In the case of EDB, industry objected at every step of the way. And under former EPA administrator Anne Burford further progress came to a virtual halt.

After EPA gave notice in 1977 that it intended to regulate the pesticide on the basis of the animal data, the process from start to regulatory finish was to last 43 weeks. The procedure bogged down immediately. Industry inundated the agency with documents disputing the findings. It also insisted that there were no good alternatives to replace the pesticide. Three years later, EPA had completed only the first step of the review.

In December 1980, just before the Carter Administration exited, the agency issued a comprehensive report that rejected almost all the criticisms raised by the chemical companies and the agricultural community and went on to propose greater restrictions on EDB's use. The report, written by Johnson, proposed severe limits on EDB's use as a soil fumigant. At that point, EPA did not call for an outright ban because it lacked firm evidence of ground water pollution. It also recommended a gradual elimination of EDB as a fumigant of stored grain, milling machinery, and citrus fruit, arguing that the potential economic losses would be negligible to farmers and others. It proposed a phaseout in 3 years to allow the food industry sufficient time to develop alternatives to the pesticide. In the long run, EPA contended, the health risks far outweighed the financial considerations. The agency came to this conclusion after it uncovered some startling findings.

For decades, it was generally assumed that the pesticide was volatile and left no residue in food. In the late 1970's, however, a number of researchers discovered that the pesticide does not dissipate. One study showed that EDB persisted in wheat with levels reaching 500 ppb 3 months after fumigation. EPA's own scientists confirmed the problem of contamination. From a USDA laboratory, EPA officials obtained batches of wheat flour that had been distributed across the country as part of federal food subsidies, including the School Lunch Program. EPA scientists reported in 1980 that all the samples contained the pesticide. (Later analyses in 1981 revealed that some of these wheat samples contained up to 4200 ppb. The samples were then made into biscuits, which registered levels averaging about 37 ppb.) Armed with the 1980 information and results from several other studies on EDB residue in grain and citrus fruit, the agency calculated that exposure to the pesticide in an average diet could increase a person's risk of cancer by a factor of 3 in 10,000. In the past, an increased cancer risk of even 1 in 1,000,000 triggered regulatory action.

The agency's recommendations were coldly received by the new Reagan appointees. Block wrote EPA, prior to Burford's arrival, that the proposed cancellation was unacceptable because alternatives could not be developed by the 3-year deadline even though EPA had concluded the industry could substitute other pest control methods for the pesticide. He said the proposal would also place financial burdens on the food industry. He did not acknowledge EPA's concern about the health risks of the pesticide through dietary exposure, except to state that he wanted more data to determine residues in food.

The pesticide issue was also stymied at EPA by John Todhunter, then head of the Office of Pesticides and Toxic Substances, who resigned in the wake of Burford's controversial departure. A hearing held in September by Representative Mike Synar (D–Okla.), chairman of a subcommittee of the Government Operations Committee, revealed that Todhunter had demanded numerous revisions of the agency's EDB report.

Florida Flip-Flops on EDB

Florida seems to want to have its cake and eat it too when it comes to the issue of ethylene dibromide. On one hand, the state's agriculture department acted aggressively and banned the sale of food products that contain minute amounts of EDB. On the other, the department is also trying to protect the state's profitable citrus and vegetable crops and has repeatedly objected to stricter regulation of the pesticide by the Environmental Protection Agency (EPA). The discrepancy between Florida's actions on the pesticide stems from the existence of two separate groups of officials within the state's department of agriculture that apparently do not see eye to eye on EDB.

One branch, the department of citrus, has consistently argued that the economic and agricultural benefits of EDB far outweigh any health hazard. It maintained this position even though studies in the late 1970's showed EDB residues persist in fumigated fruit. California, however, reported in December that recent shipments of Florida citrus were tainted with unusually high levels of EDB and expressed concern. Florida subsequently ceased shipment of all EDB-fumigated fruit to California until the federal government develops a tolerance level. This loss of market could cost the Florida citrus growers, already hard hit this winter by freezing weather, millions of dollars.

The citrus department's attitude toward EDB contrasts markedly with its bureaucratic sibling, the department of health and rehabilitative services. EDB "has no business being there [in food]," states Thomas Atkinson, chief of the state's environmental epidemiology branch. How does one account for the difference of opinion between the two departments? One possible explanation is that the ban on EDB-contaminated grain products doesn't inflict major losses on the state's own economy, while cutting off exports of EDB-fumigated fruit does.

Florida has another headache related to EDB. Farmers have used the pesticide extensively as a soil fumigant. Studies completed since last summer show that 500 wells in 12 counties have detectable levels of EDB. One well had concentrations in a range of 300 to 600 ppb, according to EPA chemist Stuart Cohen. The severity of the problem may stem from a bureaucratic snafu by the USDA and EPA. A USDA handbook contained instructions to apply the pesticide much more frequently and at higher concentrations than EPA recommends. Farmers apparently heeded the agriculture department.—**M.S.**

Synar also presented documents indicating that Todhunter and associates held private meetings with members of Florida's citrus growers and vegetable industry. Todhunter at the hearing denied he attended some of the meetings; another, he insisted, had no influence on the agency's decision-making. According to recent interviews with EPA officials, Todhunter also gutted the agency division in charge of handling these types of special pesticide reviews. Although the agency had some 90 pesticides on a roster for reexamination, Todhunter slashed the staff from 128 to about 20.

Time trickled away until last summer when California reported ground water contamination. The discovery was "the straw that broke the camel's back," said Johnson, who is still head of the agency's EDB team. After a 3-year hiatus, the agency set to work on a new set of regulations. In 2 weeks, Johnson and colleagues produced another lengthy report and pushed even harsher rules. Based on additional information, EPA calculated that the cancer risk was an order of magnitude higher than its 1980 estimates.

Again, the citrus industry, farmers, and chemical companies objected and have formally appealed EPA's action on the grounds that there are no good alternatives to the pesticide. USDA, which recently held private meetings with industry, has also intervened. Settling the differences could take another 2 years, but the revelation of EDB-tainted food and heightened public awareness may speed up the process.

EPA has said that several methods show promise as a substitute for EDB fumigation, but they have all been pooh-poohed by the agriculture department. According to EPA, citrus fruit could be treated by irradiation or another procedure that subjects fruit to cold temperatures; for stored grain, other chemicals could be applied. Florida citrus growers protest that without EDB, they will lose the $25-million grapefruit market in Japan. The Japanese government, however, has accepted citrus fruit treated by the cold storage method "for a long time," says Hisao Azuma, an agriculture official at the Japanese embassy in Washington.

Despite EPA's desire to regulate the pesticide since 1977, efforts at USDA to help farmers and citrus growers develop other methods have been meager, according to a recent study on EDB by the General Accounting Office. In a briefing submitted last spring to Representative George Brown, Jr. (D-Calif.), chairman of the Agriculture Committee's subcommittee on research, the General Accounting Office said studies by USDA have "been limited to short-term research projects. . . . This crisis-oriented research resulted in the postponement of broader-scoped, long-term research." It noted that since 1977, it has twice advised USDA to develop an agency-wide plan for research and development, but to no avail. An EPA official recently put it this way, "Without an all-out cancellation industry wouldn't consider alternatives. Now we're canceling and they're screaming there are no alternatives."

The General Accounting Office also faulted EPA's regulatory process. It cited several problems, concluding that the agency has "emphasized starting, but not completing the process, planned poorly, [and] not resolved several important policy and procedural issues. . . ."

One interesting fact in EDB's regulatory history is that the House Agriculture Committee, which has jurisdiction over pesticide use, has yet to examine the problems with the pesticide and EPA's role. Despite the strong criticisms by the General Accounting Office, Brown did not pursue the matter with his usual keen interest in pesticide problems. Some sources allege that other committee members told Brown to lay off EDB because of its wide importance to their constituents, but Brown denies this. Nevertheless, Synar and other legislators are going after the topic. Senator Dave Durenberger (R-Minn.), chairman of the oversight subcommittee of the Environment and Public Works Committee, will hold an EDB hearing on 27 January.

EPA is now pondering what to do next. On the issue of citrus fumigation, Edwin Johnson, head of EPA's Office of Pesticide Programs, says that the agency may choose a tolerance standard "at the lowest level we can set and still fumigate effectively." With grain products, Richard Johnson believes that Florida's cutoff point of 1 ppb is probably too harsh. Although he had hoped that EDB's use as a grain and citrus fumigant would have ended last summer, Johnson says 1 ppb standard would be too disruptive to the nation's economy and its food supply. "We are not dealing with a crisis [to health]," he said. Noting that the agency has already taken 7 years to achieve any substantive regulation of EDB, "Another year is not going to make that much difference." Meanwhile, the special review process at EPA has not been overhauled, its staff has not been reconstituted, and the list of pesticides slated for reevaluation continues to grow.

—Marjorie Sun

Senator Durenberger. Thank you very much. Max?

Senator Baucus. Thank you, Mr. Chairman.

Dr. Moore, why hasn't EPA acted more quickly, more forthrightly? You say you didn't go back and look at records, but both you and I know you know the controversy around EPA's failure to act more quickly. My question is you are sitting here, you are the witness. Why hasn't EPA done more, acted more quickly?

Mr. Moore. Senator, I honestly don't know.

Senator Baucus. Why don't you know?

Mr. Moore. Because I have not taken the time to find out.

Senator Baucus. Why have you not done that?

Mr. Moore. Because I have devoted my time primarily to looking forward and, indeed, in announcing cancellation and a suspension, to come up with the appropriate action that we must be coming up with.

Senator Baucus. Who are you? What is your title?

Mr. Moore. I am Assistant Administrator for Pesticides and Toxic Substances.

Senator Baucus. You are an Assistant Administrator?

Mr. Moore. Yes, sir.

Senator Baucus. Are you worried that perhaps other failures might occur?

Mr. Moore. Might occur in the future?

Senator Baucus. Within your jurisdiction of the EPA. Are you worried?

Mr. Moore. As a responsible manager, one always has to express concern that one has who is charged with——

Senator Baucus. You know the controversy around EPA's failure to act. You didn't go back to look at what happened, what may have gone wrong? You have not done that?

Mr. Moore. I have not done that.

Senator Baucus. Why have you not gone back as a good, responsible manager?

Mr. Moore. I found other things I thought were more deserving of my attention at this time.

Senator Baucus. How long have you had this job?

Mr. Moore. I was approved by the Senate November 20. I was sworn in I think around the 1st of December, sir.

Senator Baucus. So since November 20, and this is 2 months later. Doesn't a good administrator also delegate?

Mr. Moore. Yes.

Senator Baucus. Could you have delegated somebody to find out what happened, what went wrong?

Mr. Moore. I could have.

Senator Baucus. You didn't?

Mr. Moore. No. My opinion was that I have a better use or more pressing need to invest those resources than in this instance, to go back and review what happened between 1980 and 1983 with ethylene dibromide.

Senator Baucus. Frankly, Dr. Moore, I hold you responsible. As often happens, you new appointees come up and say, "I don't know." They wash their hands of it. It is a common tactic, a common technique, and I find it reprehensible, frankly. I am just putting you on notice if you come before this committee again, I am holding you responsible for past actions of your agency that occur within a reasonable period of time. I think 2 or years is a reasonable period of time. I mean, after all, you are an EPA Assistant Administrator, and you knew about the controversy, too, didn't you?

Mr. MOORE. Yes, sir.

Senator DURENBERGER. Max, would you yield just briefly on that point to find out, or I can find out, who is responsible. But in this Science article I referred to, I saw some figures saying that your predecessor reduced the number of people working on pesticide registration from something like 128 down to 20. I am just wondering if that might have something to do with the gap.

Let me ask you a more positive question; when the President the other night talked about the big budget he is going to recommend for EPA, will that restore the 108 people?

Mr. MOORE. I don't believe so.

Senator DURENBERGER. How many are you going to get back?

Mr. MOORE. I don't remember the numbers exactly. They are modest increases, but not of the magnitude you are mentioning.

Senator DURENBERGER. Would it be in the 80 ball park? I mean, this is your department. You ought to know how many folks you are going to get out of it, approximately. You are not going to get 108 back?

Mr. MOORE. The low dozens.

Senator DURENBERGER. The low dozens, like 12.

Mr. MOORE. No.

Senator DURENBERGER. Something under 24 because you used the plural; is that it?

Mr. MOORE. Senator, as you know, I am asked not to discuss the President's budget until he has announced it.

Senator DURENBERGER. It is a week from now. We have been talking about all the other things.

Mr. MOORE. I can say that there were modest increases, modest allocations into the pesticide program as far as rehires as a function of the 1984 budget, I think approximately around 40 additional people. We are in the process of fulfilling that.

Senator BAUCUS. How many did you personally request?

Mr. MOORE. Senator, the requests went in prior to my arrival. I don't know what the original request was.

Senator BAUCUS. Did you just let it go on? Did you say, "Hey, we have a problem here. We need some more people"?

Mr. MOORE. We obviously forcefully tried to present our case both within the agency while it was formulating its budget as well as when it goes from there to the Office of Management and Budget.

Senator BAUCUS. So you did present your case.

Mr. MOORE. Yes, sir; the office did.

Senator BAUCUS. Did you personally?

Mr. MOORE. I did not present the case within the agency. The budget had been developed prior to my arrival.

Senator BAUCUS. How many employees did the office request?

Mr. MOORE. I don't remember, sir.

Senator **Baucus**. Where is EDB a greater problem, if one can state it that way, among the citrus fruit use, milling operations, or grain storage?

Mr. **Moore**. I think as far as making a decision today, it is more difficult with respect to citrus based simply on the fact there are alternative uses for its use in grain. As far as I know, there are no current alternative uses for fumigation of citrus ready today.

Senator **Baucus**. Where are the concentration levels the highest, so it would be a greater problem in terms of concentration levels, apart from alternative use?

Mr. **Moore**. The data indicate that the levels are higher in edible citrus that has been treated with EDB than in, say, the edible grains that the American consumer is likely to be exposed to. The typical American exposure to fumigated citrus will be citrus either imported into this country, and it is a requirement that it be fumigated before we allow it to come in, or in those States which indeed want to keep out Mexican fruit fly or other types of fruit flies. For example, California requires Florida citrus to be fumigated before it is allowed into its State to make sure it doesn't unwittingly import some of these fruit flies.

Senator **Baucus**. So you are saying in terms of concentration levels there is a greater problem with citrus fruit use than, say, either milling operations or with grain storage?

Mr. **Moore**. Right. But the other side of the coin on that, just to make sure I am being totally objective, is that although the numbers that are in grain are lower, more people eat grain that might have residue levels in it than will consume fumigated citrus.

Senator **Baucus**. More people won't eat grain. Let's take you, for example. You are one person; right?

Mr. **Moore**. Yes, sir.

Senator **Baucus**. You have a greater problem through an average amount of citrus fruits in your diet compared with grain that would otherwise be in your diet? I am trying to separate one person's consumption.

Mr. **Moore**. The greatest exposure nationally would be presence in grain because grains are 11 percent of our diet. Wheat is 11 percent of the American diet, I am told. That is as opposed to the exposure to citrus which will only be on fresh citrus. One does not treat, for example, citrus going into juice or something like that.

Senator **Baucus**. Even though it is 11 percent versus a lower percent say for the citrus, the concentration levels are still higher in citrus?

Mr. **Moore**. Yes, sir; considerably.

Senator **Baucus**. So since they are considerably higher, what is the exposure of risk? What is the comparative exposure of risk?

Mr. **Moore**. I don't have the number.

Senator **Baucus**. Would it be equal? Would it not be equal? Roughly.

Mr. **Moore**. It seems to me the citrus risk is less because of the infrequency of the amount you consume. Again, I don't dismiss it.

Senator **Baucus**. Doctor, could you tell me how much grain that is presently in storage has been fumigated, roughly?

Mr. **Moore**. We have been trying very hard to get figures that people will say are accurate. The estimates that we get range from

5 to 50 percent of the Nation's wheat supply will contain residues, with no indication as to whether it is the 5 or 50 which is correct.

The Grocery Manufacturer's Association provided some data last week which their estimate was that 40 percent of the Nation's wheat will have residues.

Senator **Baucus**. We have some wild estimates, because the information I have is about 2 percent. Could that be accurate?

Mr. **Moore**. Well, then we can say 2 to 50 instead of 5 to 50.

Senator **Baucus**. How about 2 to 70? Why is it so difficult to get more accurate estimates?

Mr. **Moore**. Several reasons. There is no requirement for anybody to record that indeed they have treated their grain stock, whether it is an onfarm treatment, whether it is a larger storage treatment, whether it was fumigated immediately before it was sent to a miller, whether the miller treated or what he treated with.

Senator **Baucus**. The information I have is it is 2 percent and that figure came from EPA. EPA's own estimate, 2 percent.

Mr. **Moore**. That must be an older estimate. It is not a current estimate.

Senator **Baucus**. Excuse me?

Mr. **Moore**. That must be an older estimate. It is not a current estimate.

Senator **Baucus**. When grain in storage is fumigated, it is my understanding it is fumigated with a solution of which only about 20 percent contains EDB; is that correct?

Mr. **Moore**. Some of the material that is used—you say for fumigation or for milling?

Senator **Baucus**. Fumigation.

Mr. **Moore**. For fumigation, the product that typically is used I am told today is primarily composed of other products other than EDB. The EDB level is typically down to 5 percent.

Senator **Baucus**. Of the total solution?

Mr. **Moore**. Yes.

Senator **Baucus**. Of the total solution, only 5 to 20 percent is EDB?

Mr. **Moore**. One-twentieth or so.

Senator **Baucus**. So that is a fairly small percent of the total solution.

Second, the EPA information I have is that 2 percent of the grain in storage has been fumigated, so that is a pretty small percentage.

Third, we have established that EDB expected in grain stored, as I understand you to say, is less of a problem than citrus fruit use.

Adding all three together, I am trying to establish there is less of a basis or foundation for the "public scare" about EDB in grain storage. Would it be fair to say there is probably some problem with respect to grain storage but that it is not perhaps as cataclysmic as some sensational reports make it out to be?

Mr. **Moore**. I obviously don't know what all of the sensational statements are that are being made. Some of the ones I have either by inference heard or people made I think are sometimes somewhat sensational or overpredicting doom and gloom.

That is not to say I think it should be allowed to remain in our food supply, either. Indeed, we should move to take it out.

Senator **Baucus**. I agree. It is a problem we have to take care of. It is like anything else, there is little or no balance. Sometimes I think some of the stories, like otherwise I think the problems in grain storage, have been overstated. It is a problem, but it has been overstated.

Mr. **Moore**. I would like to make one more statement about the degree of contamination or levels of contamination. We do have indications there are 20-odd States now that are in the process of forwarding information to us in addition to what we already have received. Hopefully in the composite of that we might be able to get a firmer figure of whether it is the 2 percent or 40 percent, whatever the case may be.

Senator **Baucus**. Dr. Moore, the document I have here is from the Office of Pesticide Programs, EPA, September 27, 1983. It is EDB. That is the whole subject. Turn to page 199. This is again September, just a few months ago. It states that. "Approximately 225 million bushels of stored grain, or about 2 percent of the grain produced in the country, are treated annually with fumigants containing EDB."So that is a September EPA statement.

Mr. **Moore**. That is a September issuance. It doesn't necessarily mean that all of the data that are contained in it represent September of 1983 data. It could be referring to old data.

Senator **Baucus**. We have to take the conclusion, though, of the agency, it seems to me. What else do we go on.

Senator **Durenberger**. I think just for the record you are reading from an appendix which is a 1980 document, an appendix to a September 27 report. But it does come from EPA and it does say 2 percent.

Senator **Baucus**. It still says September 1983.

Senator **Durenberger**. Any more questions?

Senator **Baucus**. No.

Senator **Durenberger**. Senator Abnor, do you have any questions of the witness?

Senator **Abdnor**. No. I apologize for coming in so late. I don't have a statement for the record, but I might be interested in asking a few questions when my turn comes.

Senator **Durenberger**. I am going to excuse Dr. Moore now, so if you have any questions of him, this would be the time.

Senator **Abdnor**. I am sorry. I guess I missed all of your testimony. Just what have you done on this right now? What is the situation? How far have you gone into this?

Mr. **Moore**. Senator, we are basically in a situation where we have announced suspension of its use as a direct injection in soils. That accounts for 90 percent of the agricultural use of ethylene dibromide. We also intend to deal with stored grain and milling of grain.

Senator **Abdnor**. It can be used on stored grain?

Mr. **Moore**. We announced its cancellation of that use. That cancellation notice had been appealed by some people so it is allowed to continue in use during that process. We are now in the process of considering whether we want to let our cancellation action stand or whether we want to take a more rigorous approach and announce suspension of its use in that regard.

Senator **Abdnor**. What happens to the grain that is in storage that has been treated and still has a couple of years to run in storage under the programs that people in Agriculture have entered into? Have you made a decision on that?

Mr. **Moore**. Our feeling is that in trying to give guidance of what tolerance levels or what residue should be allowed while the Nation's grain supply clears itself, we are aware of the fact that wheat, for example, typically can be 3 and 4 years old before it makes its way to the consumer's table. Indeed, that should be factored in.

Senator **Abdnor**. You are. That is what I want to know.

Mr. **Moore**. Yes.

Senator **Abdnor**. Do you have hardcore, solid evidence that this grain has been moderately treated or is harmful to some people?

Mr. **Moore**. We do have a growing body of data that clearly suggests there are residue levels of EDB in a variety of products that are derived from grains.

Senator **Abdnor**. I am not trying to say there isn't. I am talking about as used on grain. That is a heck of a lot difference from dumping solid stuff on the ground.

Mr. **Moore**. Yes, sir.

Senator **Abdnor**. There are variations of amounts.

Mr. **Moore**. Senator, our position is that the risks that are associated with the presence of ethylene dibromide in grain are unacceptable in the long term and, indeed, we should be phasing it out.

Senator **Abdnor**. I wouldn't question that, if you have evidence that strong that proves that it is harmful, but we are really not that sure, are we yet?

Mr. **Moore**. Senator, our approach is trying to look at the levels which one should tolerate while the Nation's grain supply is allowed to eliminate itself through natural processes of residues that may be present rather than just a wholesale ban of all.

Senator **Abdnor**. You are EPA, you are the one that said only 5 percent of storage grains has been treated this way. Where does that figure come from?

Mr. **Moore**. Senator Baucus was suggesting it was 2 percent.

Senator **Baucus**. Senator Abdnor, it is in a document EPA puts out. The document itself is dated September 27, 1983, and it says 2 percent. That is an appendix to another document which is dated 1980. So maybe it is 1980 data. The trouble is, it is appended as an appendix to a 1983 document. So it is the latest information according to this document.

Senator **Abdnor**. What is the alternative to using this? It is used for insect control and many different things. Are there different chemicals on the market that are absolutely safe?

Mr. **Moore**. There are other chemicals on the market that can replace EDB as a fumigant for stored grain or spot fumigation of milling equipment.

Senator **Abdnor**. Are they being used more and more, do you know?

Mr. **Moore**. It is my understanding they are.

Senator **Abdnor**. I am not going to quarrel if it is 2 percent or 5 percent. I am in a farm area and I am a farmer myself. You are going to have a heck of a time telling me about stored grain. At least in this last year bugs were coming out all over the country. It was a choice of having the grain just hollowed out and nothing left to chaff or treat. I don't know what they treated it with. I have to find out. But it could be a very serious thing. I just want to make sure we know what we are talking about before we panic and jump into this thing and do all kinds of great things in the name of saving the people. I am for that, but I want to make sure we know what we are doing before we act.

Senator **Durenberger**. I think the three of us here, coincidentally I guess, represent three of the largest grain producers in the country.

Before you got here, Jim, we did go through some of the areas where even if EPA were to act, in the next week or so in a way that some might consider precipitous, there has been built into this process of final determination a wide variety of protections that we are trying to find out exactly how they work and how we get the best information.

Are there any other questions of this witness?

Senator **Baucus**. Yes; I just want to help out Dr. Moore a little bit. I have a document here which is dated 1981. It is a memo of an internal meeting, about the problem with EDB, and EPA is going to put out regulations and take action in a few months. This is December 22, 1981. I will make it part of the record. It is a meeting called "EDB Meeting, December 22, 1981, Minutes." Then it lists the people in attendance, discussion, so forth. Paragraph 5 says, "EPA is going forward with establishing EDB residue levels in fruit and that level should be out in several months. EPA would then be required to assure the levels are being met." Again, that is December 22, 1981.

I have some other documents along the same lines, and I will put those as part of the record, too.

Senator **Durenberger**. I would withhold any objection to putting it in. I think maybe we ouqht to qet the whole file in the record for that period of time since the witness has indicated he wasn't around and didn't have time, or whatever it was, to pull it out himself. (See pp. 29–75.)

Senator **Baucus**. I helped do his research. You can do it more quickly that way.

Senator **Durenberger**. Thank you very much.

[The 1981 memo referred to by Senator Baucus follows:]

Ethylene Dibromide Meeting December 22, 1981

Minutes

Attendance

1.	Mary White	OSHA Health Standards
2.	David Logan MD	OSHA Office of Medical Affairs
3.	Steve Mallinger	OSHA Office of Field Coordination
4.	Joe Penetta	EPA
5.	Bill Helms	USDA - APHIS
6.	Bob Kenney	United Fresh Fruit and Vegetable Assn.
7.	Mike Kies	Food Market Institute
8.	Mike Lewis	International Longshoremen Workers Union
9.	Debby Burkowitz	Food and Beverage Trades (AFL-CIO)

Others invited, but could not attend were:

1.	R.V. Durham	Teamsters
2.	Bill Olwell	United Food and Commerical Workers

Discussion: 11:30AM

1. Reviewed data from initial tests run (truck from Flordia to California on November 20, 1981). Discussed adsorption problems with tubing and how it may have altered results of area samples inside the trailor. However, this tubing was not used for personnel samples. Mr. Mallinger was asked to check if all sampling results were provided, including California.

2. Ms. Burkowitz asked about different agency roles including USDA, EPA, OSHA, and A.D. Little and what will happen to the information after it is obtained.

3. The Food Market Institute and United Fresh Fruit and Vegetable Association believe that a good deal of fruit is either being fumigated after it arrives in the U.S. or is being fumigated before it is shipped. Two examples given were; citrus coming from Mexico that substantially supplies the western states during January and February, and some foreign fruit coming in New York and being fumigated in New Jersey. Joe Penetta indicated that he would assemble and supply that data to whomever desired but thought that it was a very low amount.

4. Bill Helms indicated that the USDA was opening up negotiations with Japan on the requirement to fumigate all fruit sent there from California. Less than 1% of the crop land now has any trap finding of the Medfly. Texas does not have to fumigate any of their fruit going to Japan.

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5. Joe Penetta indicated that EPA is going forward with establishing a EDB residual level in fruit and that level should be out in several months. FDA would then be required to ensure the levels are being met.

6. Bill Helms presented to the group that all the agencies involved wanted to try additional shipments from Flordia and Texas (if Texas has to go back to fumigating on January 1). He asked for cooperation from all people involved. Mr. Helms indicated that the week of Jan. 4, would be the best time. Mr. Kies indicated he would attempt to set up a shipment that week. In response to Ms. Burkowitz's question of how many more shipments, Mr. Helms responded that it would have to be at least enough to statically determine that methods are correct and that the combined number of test runs for Texas and Flordia may be as high as 50. Trailer modifications and additional tests for air flow and temperature would be taken on the the next test.

Meeting ended at 1:00PM.

Steve Mallinger
Office of Field Coordination

Senator **Abdnor**. I would like to ask you one more question. Have you set tolerance or action levels so low that some of our current grain supplies would exceed the limit and those who own this grain are going to incur substantial financial losses? Have you either amongst yourselves or in discussion with USDA given any consideration to what the Federal Government might do to ease the economic burden which may result from the agency's decision in this matter?

Mr. **Moore**. We have had discussions with USDA on the implications of losses of incremental segments of the Nation's grain for human consumption. We are also in receipt of documents prepared by others that point out the consequences of such action. We have not, to my knowledge, sat down with USDA or somebody else and said if indeed such action was to be taken, how could one ameliorate the economic consequences say for the person whose grain was not available to the market.

Senator **Abdnor**. I could not urge you enough that in your deliberations and discussions you come up with something so that we don't fault the individual or the group. I know that if it proves to be that critical, then something has to be done, and they should take into consideration how they are going to ease the burden on those people who suffer for this through no fault of their own. Thank you.

Senator **Durenberger**. Thank you very much.

Thank you, Dr. Moore. I appreciate your testimony.

[The file previously referred to by Senator Durenberger follows:]

[illegible]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OCT 16 1981

OFFICE OF TOXIC SUBSTANCES

NOTE TO: Dr. John Hernandez, Jr.
Deputy Administrator

RE: Ethylene Dibromide - EDB

In response to your request to Dr. Todhunter, I have attached the following information on EDB.

- A summary of the information we have on the residues of EDB in fumigated fruit which discusses the current tolerance level for EDB;
- A copy of a statement summarizing the Agency's current position on EDB which was provided to John McClaughry of the White House on October 9, 1981; and
- A copy of a memorandum from Mark D. Cowan, Deputy Assistant Secretary of Labor, to Dr. Todhunter, which discusses potential exposure from handling fumigated commodities.

Ed Johnson, Director, Office of Pesticide Programs and Marcia Williams, Director, Special Pesticide Review Division, are ready to provide any additional information you would like on EDB.

Attachments

Paul Lapsley
Paul R. Lapsley, Chief
Chemical Review Branch #4
(557-7781)

cc: Todhunter, J.
Johnson, E.
Williams, M.

→ Dr. Hernandez –
Here [illegible] integrated statement
JT
John A. Todhunter

In December, 1980, the Environmental Protection Agency (EPA) issued a proposed decision on the continued use of ethylene dibromide (EDB), a fumigant used on fruits and other commodities and crops. This proposed decision was based on an investigation into the risks and benefits related to each of the pesticidal uses of EDB. The EPA proposal was that if a suitable alternative could be developed, the use of EDB as a fumigant in fruit should be discontinued by 1983. This proposal reflected the EPA's concern that studies demonstrating that EDB causes cancer and other adverse effects in animals may indicate the chemical could also pose a risk to humans eating EDB-treated fruit over a lifetime and that if safer alternatives could be developed that humans should not be exposed to this potential risk. The 1983 date was selected to allow the Food and Drug Administration (FDA) sufficient time to approve the use of irradiation as an alternative method. The EPA is continuing to work with FDA and others to pursue the development of irradiation and other alternatives.

Since the time of EPA's December report on EDB, the Medfly outbreak in California required officials in that state to also treat California fruit intended for export to Japan. This was necessary because the Japanese would not accept the exported fruit unless it had been treated with EDB. While none of the California treated fruit is intended for domestic consumption, concern has arisen anew about potential risk from EDB treated fruits from Florida and other states that are being shipped to California. Even if the California treated fruit was intended for domestic consumption, the potential risk posed by the one to two year interval of treatment necessary to deal with the Medfly would not pose unreasonable risk assuming that the residue levels are similar to those measured previously in Florida and Hawaiian treated fruit.

Because of the recent level of concern, the EPA has initiated a joint program with California to analyze EDB treated fruit from other states. This treated fruit is being collected from produce distributors in California. A part of this monitoring program will measure the EDB residues in fruit as a function of time from fumigation to availability in the market. These data are expected to be available by the end of November. Should these data reveal an unanticipated short term risk which is unacceptable, the EPA will propose measures to reduce exposure and risk.

Preliminary results of this cooperative monitoring have indicated that the risks may be even lower than the Agency had anticipated. The December 1980 risk analysis used residue data provided by the California Department of Food and Agriculture (CDFA).

In 1979 CDFA measured levels of EDB in fruit received at warehouses after shipment from Florida. In 9 samples of whole fruit tested 8 to 18 days after fumigation, EDB residues ranged from 0.06 to 6.35 ppm, with an average residue level of 1.37 ppm. These residue levels were used in supporting the proposal in the EDB Position Document 2/3 to cancel use of EDB on citrus because of unreasonable cancer risks.

CDFA is currently working with the EPA Beltsville Lab to monitor levels of EDB in citrus taken from California supermarkets and also in freshly fumigated citrus. CDFA has obtained the following preliminary results (actual EDB, not inorganic bromide):

Fruit Taken from Supermarkets* (average ppm EDB)

	Pulp	Peel	Total
Oranges	.048	0.29	0.1
Grapefruit	.051	0.42	0.2
Lemons	none detected	0.007	none detected

*6 samples per group

Freshly Fumigated Fruit* (average ppm EDB)

	Pulp	Peel	Total
Oranges	0.59	17.23	5.74
Lemons	0.77	25.7	7.1

(no grapefruit are fumigated in California)

*4 samples per group

We are working with CDFA to jointly analyze these data and additional data from samples of fruit which will be stored at various temperatures for several different time periods. We will then determine a decay curve for EDB residues in fruit as a function of time after fumigation.

While EPA is not certain as to why these residues are substantially lower than those previously measured, it is clear that EDB residues could be about 10 times lower for whole fruit than previously estimated. This, if substantiated, could reduce the previously estimated dietary risks by an order of magnitude (10 times). Given that the pulp of the fruit is what is normally eaten domestically and that the previous risk estimate was for whole fruit, the pulp residue measurements indicate that dietary risks could be nearly 30 times lower than what EPA originally estimated. These residue values will have to be substantiated before EPA can be confident that these apparent risk reductions are real. The ongoing study, which is aimed at determining residue decay rates, should help to answer this question.

Currently, EPA is working with other government agencies as a member of a multi-agency working group to explore measures to respond to the concern over EDB. These measures are intended to reduce any potential risk which might exist from treatment of fruit with EDB and include possible reduction of the amount of EDB used to fumigant fruit, insuring a suitable interval of time between treatment and marketing of fruit, and adequate aeration and ventilation of vehicles during transport of treated fruit.

John Hernandez

CONCERNS OVER FUMIGATED FRUIT EXAGGERATED

National Science Advisor, Dr. George Keyworth, announced today there is little significant risk to the general public from short term use of ethylene dibromide (EDB) on fruit to eliminate several types of fruit flies, including the Mediterranean fruit fly.

The four-member Interagency Regulatory Science Group, composed of the U. S. Department of Agriculture, Environmental Protection Agency, Food and Drug Administration and Occupational Safety and Health Administration, has been conferring because of recent concern surrounding the continued use of EDB to fumigate agricultural commodities.

EDB, a commonly-used fumigant since 1953, is proposed by EPA for withdrawal from use when a suitable alternative is developed. The material is currently registered and approved for use on various commodities such as citrus and tropical fruits. Recent concern for worker safety and residues on fruits and vegetables going to consumers has caused disruption in shipping and marketing channels.

Recent interest has been heightened because of the expanded use of EDB in California as a fruit and vegetable treatment against the Mediterranean fruit fly and recently-released scientific evidence that EDB causes cancer and reproductive damage in animals. Labor unions and other workers handling fumigated commodities both in the U.S. and foreign countries have expressed concern about handling treated products.

Since use of EDB will continue for only a limited time there is minimal risk to handlers and consumers from EDB-fumigated commodities. Mechanical means such as ventilation and lengthened intervals between treatment and the marketplace allowing for maximum dissipation of the material before it is handled and eaten will further reduce any residues.

USDA
EPA
FDA

October 30, 1981

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

November 4, 1981

MEMORANDUM

SUBJECT: Weekly Activity Report

FROM : Director, Office of Pesticide Programs

TO : Assistant Administrator
for Pesticides and Toxic Substances

FEDERAL REGISTER FORECAST

The following final rules are scheduled for publication in the *Federal Register* during the forthcoming months:

- **Hexakis**: 40 CFR Part 180 (PP 0F2406/R351)

  This regulation will establish a tolerance for the combined residues of the insecticide Hexakis distannoxane and its metabolites calculated as Hexakis distannoxane in or on the raw agricultural commodity strawberries at 10.0 parts per million (ppm). This rule will establish the maximum permissible level for the combined residues of Hexakis and its metabolites in or on strawberries.

- **Carbofuran**: 40 CFR Part 180 (PP 6F1787/R367)

  This rule, requested by FMC Corporation, will establish a tolerance for the combined residues of the insecticide Carbofuran and its metabolites in or on the raw agricultural commodity grapes. This regulation will establish the maximum permissible level for residues of Carbofuran.

EDB

On October 27, 1981, the Interagency Work Group met at the White House with citrus growers from Florida, California, Texas, and Hawaii. The citrus growers had requested a prompt statement from the Federal agencies involved in regulating EDB regarding recent action by California/OSHA which the growers felt was unduly burdensome on interstate commerce. The Work Group has drafted a statement, which will be issued this week, on EDB risks to consumers and workers.

On October 28, 1981, the Work Group met with attorneys representing the Sunkist growers. The Sunkist representatives reaffirmed the need for a government statement on EDB risks because California/OSHA requirements to protect supermarket workers are disrupting commerce in California.
The California Department of Food and Agriculture (CDFA) is continuing the collection of citrus samples to measure EDB residues. The EPA Beltsville Laboratory has analuzed the first group of samples and expects to receive another shipment this week. The results will be used to determine expected residues of EDB in fruit at various points in time after fumigation. The Sunkist representatives also agreed to share the results of a recent study of EDB residues in citrus. (Panetta, x77451)

TOXAPHENE TOXICITY TO CATTLE

Jay Ellenberger (RD) has been assistaing Linda Fentiman (OGC) with a discovery of information related to Toxaphene's toxicity to cattle and the USDA veterinary quarantine of scabies on cattle. This is being done for a lawsuit between cattleman, George Neary and the State of California and USDA veterinarians who supervised the quarantine cattle dipping of Neary's cattle. (Ellenberger, x72386)

BEE REPELLENTS

Questions have arisen as to whether N-butyric anhydinde and benzaldehyde are subject to registration when used solely as agents to chase bees out of portions of the beehive in order that honey can be harvested. Under existing policy, it was determined that since honey bees are raised for their honey and are expected to reside in beehives, they are not pests in this instance. Therefore, products used solely to move honey bees from one location to another in or around hives are not pesticides. Bee Go and Benzaldehyde have been registered solely for this purpose, but since they were registered in error, letters are being prepared to deregister them. (Tavano, x72690)

MISSISSIPPI PROJECT--AGRICULTURAL STUDY

The Mississippi Pesticide Hazard Assessment Project monitored four pairs of juvenile/adult workers during harvesting of fall cucumbers at a site near Louisville, Mississippi on October 10-13, 1981. The chemical that was monitored was Carbaryl. A vegetable farming cooperative has been established in this area and consists of families who grow truck crops such as peas, peppers, cucumbers, and okra. All of the labor in this activity is supplied by the families, including the use of children in all phases of the agricultural activities. The purpose of the field study was to evaluate the dermal and inhalation exposure of adults and juveniles during the harvesting of the cucumber crop. The samples that were collected included body patches, gloves, air, foliage, soil, and pre- and post-urine samples. This is the first of a series of Department of Labor studies that is to be conducted by the Mississippi Project in FY 82. (Fuller, 8-677-4295

__Travel and Speeches__

I will be in the office the remainder of this week. For the week of November 9, 1981, I will be in the office.

Ed Johnson

Edwin L. Johnson

cc: Dr. Bracken
Dr. Hill
Dr. Muir
Dr. Wells
Ms. Vogt
OPP Division
ODAA Staff

EX12

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SMALL BUSINESS

CHAIRMAN, SUBCOMMITTEE ON SPECIAL
SMALL BUSINESS PROBLEMS

Congress of the United States
House of Representatives
Washington, D.C. 20515

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May 27, 1982

Dr. John Todhunter
Asst. Administrator for
Pesticides & Toxic Substances
Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Dear Dr. Todhunter:

I appreciate your having Dr. Wells of your staff call my office so promptly this morning to confirm that you have agreed to delay issuing the rule on EDB until July, at the earliest, pending consultations with OSHA, and with myself and Senators Chiles and Hawkins.

Dr. Ismail has told me that he will send you promptly data which should help alleviate your concerns regarding Florida's program. I would simply add the comment that I hope that you will be able to promptly rectify this situation, for both environmental and economic reasons.

First, we do not have any practical alternative to EDB; second, the proposed annual appeal system simply won't allow rational planning or marketing operations, and I leave it to your imagination what the effects of such an uncertain situation would be on our exports, particularly to Japan.

Regarding Japan, I trust that you have already informed them that you are delaying the EDB rule, pending further study. I can tell you from experience that the Japanese do not require much of an excuse to disrupt our export program, and that this proposed EDB ban, or an annual appeals process, would give them a reason on a platter.

Many thanks for your prompt attention to this matter of such vital importance to the economic well being of Florida. My staff will be in contact with yours regarding the timing of our meeting.

Sincerely,

Andy Ireland

API:cn

ANDY IRELAND

EX 13 2179

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COMMITTEES:
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May 27, 1982

The Hon. Ann M. Corsuch
Administrator
The Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Dear Madam Administrator:

I understand that on the basis of a meeting yesterday between Dr. Todhunter of your staff, and representatives of the Florida fruit and vegetable industry, EPA has agreed to delay issuing a rule which would have banned the use of EDB starting in 1983.

Dr. Wells of Dr. Todhunter's office informed my staff today that EPA would delay at least until July, pending consultation with OSHA, and receipt of details of Florida's EDB program from our experts.

Let me say that I am very pleased by your department's action in this situation, but let me also say very strongly that I hope that the delay will produce a reassessment of any plans to ban EDP, since I think that the facts will indicate to you that such a ban is justified on neither environmental nor economic grounds.

I have been following this issue closely, and am satisfied that you will find that the facts show that Florida's program is safe, in addition to being the only practical alternative. In addition, I would comment that if the EPA were to persist in a ban of EDB, the economic consequences to our exports, particularly to Japan, would be disasterous.

I understand that as soon as the consultations with OSHA have taken place, Dr. Todhunter has agreed to my suggestion that we meet with Sen. Chiles, Sen. Hawkins and his staff to review the entire matter. Let me say that I look forward to this meeting, and to clearing up this situation in a way which reflects the best interest of us all.

Many thanks for your attention to this matter.

Sincerely,

Andy Ireland

ANDY IRELAND

API:cn

June 10 1982

MEMORANDUM

TO: John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides and Toxic Substances (TS-788)

SUBJECT: Ethylene Dibromide (EDB) Position Document
(FD-4) - ACTION MEMORANDUM

On December 14, 1977 the Agency issued a Notice of Rubuttable Presumption Against Registration (RPAR) and continued registration of pesticide products containing EDB, which is used as a soil and commodity fumigant. The RPAR was based on oncogenic, mutagenic and reproductive effects. The issue of oncogenicity was founded on a study sponsored by the National Cancer Institute which reported a statistically significant increase of squamous cell carcinomas in the forestomach of rats and mice. Metastases of these tumors were reported.

Regarding mutagenicity, the Agency concluded that EDB is a positive mutagen in prokaryotic (microbial) and eukaryotic (higher forms including mammels) organisms for point (gene) mutations with and without mammalian metabolic activation. Reproductive disorders were noted in several studies of bulls and rodents which established that EDB could adversely affect mammalian reproductive development by interfering with the production of male gametes and the development of embryos. Adverse effects in hen egg production were also noted.

Ethylene dibromide is registered as a preplant soil fumigant for citrus, cotton, peaches, peanuts, pineapple, tobacco, and vegetables. It is also registered as a commodity fumigant for stored grain; quarantine fumigation of citrus, tropical fruits and miscellaneous vegetables under USDA/APHIS programs; spot fumigation of grain milling machinery; and for the fumigation of felled logs, termite control, beehive supers and honeycombs, vault fumigation, and quarantine fumigation of sod, bare root plants, balled containerized plants and potting or bench soil under the APHIS Japanese beetle quarantine program.

On December 10, 1980 the Agency issued the Position Document 2/3 explaining the Agency's analyses of risks and benefits attributable to the presticidal uses of EDB. It also presented the Agency's proposed regulatory actions regarding the various uses of the pesticide.

The human health risks of EDB-induced oncogenicity, mutagenicity and reproductive abnormalities remain unrebutted. However, the economic benefits of some uses are high and suitable alternatives are not currently available. Therefore, the Agency's decision, proposed in PD 2/3, has been modified to continue use of EDB where workers and the general public can be adequately protected.

The Agency received information from the Scientific Advisory Panel, the Secretary of Agriculture, registrants, user groups, and the public. Based on that information, some aspects of the risk and benefit assessments, and the regulatory requirements have been modified. The remainder of the analyses presented in PD 2/3 remain unchanged. The comments of substance and the appropriate revisions are presented in the PD 4.

The Scientific Advisory Panel met on March 25-26, 1981. The Panel basically agreed with the PD 2/3, although additional studies of the efficacy of irradiation, the alternative to citrus fumigation, were recommended. Their comments are addressed in the PD 4. The U.S. Department of Agriculture's comments are also included in the PD 4.

The Position Document 4 would: 1) maintain but restrict the use of EDB for preplant soil fumigation with label modifications requiring respirators and protective clothing; 2) cancel the use for fumigating stored grain; 3) maintain but restrict the use for spot-treating grain milling machinery with label modifications requiring respirators and protective clothing, aeration of treated mills before reentry is permitted, and imposition of a restriction of no detectable residue of EDB on flour; 4) require amendments in the labels restricting the use of EDB products used for fumigating citrus, vegetables and tropical fruit effective 30 days after the publication of this decision in the Federal Register followed by cancellation of this use on July 1, 1985; 5) cancel the use for fumigating felled logs; 6) continue the low volume uses (termite control, beehive supers and honeycombs, vault fumigation, and APHIS Japanese beetle control) provided label modifications are made and monitoring data are supplied.

If you approve the recommended decision, please sign this action memorandum in the space provided below. Also, please sign the accompanying Federal Register Notice which, together with the Position Document (PD 4), explains the Agency's proposed action in detail.

/s/ James M. Conlon

Edwin L. Johnson, Director
Office of Pesticide Programs

Approve ____________________

Disapprove ____________________

Date ____________________

(Note: This memorandum has been retyped in order to obtain a reproduceable copy.)

MEMORANDUM

TO: The Administrator (A-100)
The Deputy Administrator (A-101)

SUBJECT: Ethylene Dibromide (EDB) - INFORMATION MEMORANDUM

ACTION

Today I signed the Notice of Determination Concluding the Rebuttable Presumption Against Registration (RPAR) of ethylene dibromide (EDB). On December 14, 1980 the Agency issued a Notice of Rebuttable Presumption Against Registration of pesticide products containing EDB, which is used as a soil and commodity fumigant. The RPAR was based on oncogenic, mutagenic and reproductive effects. The concerns regarding oncogenicity were founded on a study sponsored by the National Cancer Institute which reported a statistically significant increase of squamous cell carcinomas in the forestomach of rats and mice. Metastases of these tumors were reported. Regarding mutagenicity, the Agency had information indicating that EDB is a positive mutagen in prokaryotic (microbial) and eukaryotic (higher forms including mammels) organisms for point (gene) mutations with and without mammalian metabolic activation. Reproductive disorders were noted in several studies of bulls and rodents which established that EDB could adversely effect mammalian reproductive development by interfering with the production of male gametes and the development of embryos. Adverse effects in hen egg production were also noted.

Ethylene dibromide is registered as a preplant soil fumigant for citrus, cotton, peaches, peanuts, pineapple, tobacco, and vegetables. It is also registered as a commodity fumigant for stored grain; quarantine fumigation of citrus, tropical fruits, and miscellaneous vegetables under U.S. Department of Agriculture/ Animal and Plant Health Inspection Service programs; spot fumigation of grain milling machinery; and for the fumigation of felled logs, termite control, beehive supers and honeycombs, vault fumigation, and quarantine fumigation of sod, bare root plants, balled containerized plants and potting or bench soil under the APHIS Japanese beetle quarantine program.

On December 18, 1980, the Agency issued Position Document 2/3 explaining the Agency's analysis of risks and benefits attributable to the pesticidal usesof EDB. It also presented the Agency's proposed regulatory actions regarding the various uses of the pesticide.

Our concerns regarding EDB-induced oncogenicity, mutagenicity and reproductive abnormalities remain unrebutted. However, the economic benefits of some uses are high and suitable alternatives are not currently available. Therefore, the Agency's proposed decision for an interim period until suitable alternatives are available, has been somewhat modified to allow continued use of EDB where workers and the general public can be adequately protected.

The Agency received information from the Scientific Advisory Panel, the Secretary of Agriculture, EDB registrants, user groups, and the public. Based on that information, some aspects of the risk and benefit assessments and the regulatory requirements have been modified. The remainder of the analyses presented in FD 2/3 remain unchanged. The comments of substance and the appropriate revisions are presented in the FD 4.

Our decision, therefore, is to: cancel the uses for fumigating stored grain and felled logs immediately; require use restrictions as amendments to the labels of EDB products used for fumigating citrus, vegetables and tropical fruit effective 30 days after the publication of this decision in the Federal Register, followed by cancellation of this use on July 1, 1985; and to continue registration for preplant soil fumigation, spot fumigation of grain milling machinery and the low volume uses for termite control, beehive supers and honeycombs, vault fumigation and Japanese beetle control.

A copy of the position document is attached for your information.

John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides
and Toxic Substances

Attachment

(NOTE: This memorandum has been retyped in order to obtain a reproduceable copy.)

ROUTING AND TRANSMITTAL SLIP

Date 6/16/8

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. William Dickinson	WD	6/15
2. Ed Johnson		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

In a June 10 EDB meeting with Marc Cowan of OSHA, Todhunter agreed to defer issuing the final decision on EDB until August so that OSHA could simultaneously issue their proposed rule setting a new standard for EDB exposure in the workplace. Although I suggested to Todhunter after the meeting that we may want to announce our decision before OSHA does, so that the unions can focus their energies on OSHA once they see we've deferred to OSHA's authority in the workplace, it appears there may be more compelling reasons for not waiting for OSHA: they

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post) Paul R. Lapsley	Room No.—Bldg.
	Phone No. X774

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

won't be able to issue their proposed rule until October. The attached memo to Todhunter would inform him of the status of the OSHA rulemaking as we've heard it from the OSHA staff responsibl for developing the rule. Todhunter requested in the meeting that we keep in close touch with OSHA staff to let him know how their schedule might change so I expect that he would want to see something like the attached memo.

Paul L 6/17

JUN 21 1982

MEMORANDUM

TO: John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides and Toxic Substances (TS-788)

SUBJECT: EDB Final Decision -- Coordination with OSHA

In following up on your June 10 EDB meeting with Mark Cowan of OSHA, Joe Panetta spoke with Nancy Adams, the OSHA Project Manager, concerning your agreement with Cowan to delay publication of the PD-4 until August.

According to Adams, who was out of town at the time, Cowan was working from an old schedule when he stated that OSHA will be prepared to issue a proposed rule on EDB in August; the revised schedule calls for publication of a proposed rule in October. This week, OSHA began a monitoring study in warehouses and packing plants handling EDB-treated fruit. The study will not be completed until August. The results will play an integral part in the development of the OSHA position; however, Adams will not be able to develop the position until the study is completed.

In addition to this delay, there is the distinct possibility that the OSHA position will be subjected to OMB review, pushing the issuance of a proposed rule beyond November. We would have no OMB hurdles.

In conclusion, it appears quite unlikely that OSHA will be prepared to publish a rule in August. The scheduled October date, while a possibility, is also an optimistic target.

/s/ James M. Conlon
Edwin L. Johnson
Director
Office of Pesticide Programs

cc: J.W. Conlon
W. Wells

SPRD:JPanetta:bm:X77451:Rm.711:6-12-82:revised:6-18-82

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MAN, SUBCOMMITTEE ON SPECIAL
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Congress of the United States
House of Representatives
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2015 SOUTH FLORIDA AVENUE
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TS/Todhunter
cc AI-Weber
RD
IA
Reg 4
AF

June 20, 1982

Dr. John A. Todhunter
Assistant Administrator for Pesticides
and Toxic Substances
Environmental Protection Agency
Washington, D.C. 20460

Dear Dr. Todhunter:

Thank you for your reply to my earlier letters concerning EDB, and suggesting that it is now time for you to join me, and Senators Chiles and Hawkins to see just where we go from here in this.

Chris Nelson of my staff has filled me in on his long conversation with you. I take it that while unofficial, I can now be assured that the immediate ban in 1983 of EDB will not take place, and we will now be discussing plans for 1985 at the earliest.

As I have said before, and will say again, I really do not understand why it is either necessary or prudent for EPA to be attempting to ban a pesticide which you say is safe if correctly used, and for which there is no alternative. Perhaps this is one of the areas you can clarify when we meet after the July recess.

I was glad to note in your letter awareness of our economic concerns, particularly regarding Japan. I would hope that in the future, you will coordinate closely with USDA on this aspect of your proposed rule-making as it cuts across jurisdictional lines in the Administration.

Finally, I appreciate your increasing coordination with OSHA, as it is clear that if the primary problem with EDB is in the workplace, it is with OSHA that we must ultimately work out a rational solution to this problem.

Many thanks again for writing. I look forward to meeting with you soon.

NOTE:
See AI-2190

Sincerely,

Andy Ireland

API:mcc

IF RESPOND TO: ☐ WASHINGTON ☐ WINTER HAVEN ☐ BRADENTON ☐ SARASOTA ☐ LAKELAND

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 21 1982

MEMORANDUM

TO: John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides and Toxic Substances (TS-788)

SUBJECT: EDB Final Decision -- Coordination with OSHA

In following up on your June 10 EDB meeting with Mark Cowan of OSHA, Joe Panetta spoke with Nancy Adams, the OSHA Project Manager, concerning your agreement with Cowan to delay publication of the PD-4 until August.

According to Adams, who was out of town at the time, Cowan was working from an old schedule when he stated that OSHA will be prepared to issue a proposed rule on EDB in August; the revised schedule calls for publication of a proposed rule in October. This week, OSHA began a monitoring study in warehouses and packing plants handling EDB-treated fruit. The study will not be completed until August. The results will play an integral part in the development of the OSHA position; however, Adams will not be able to develop the position until the study is completed.

In addition to this delay, there is the distinct possibility that the OSHA position will be subjected to OMB review, pushing the issuance of a proposed rule beyond November. We would have no OMB hurdles.

In conclusion, it appears quite unlikely that OSHA will be prepared to publish a rule in August. The scheduled October date, while a possibility, is also an optimistic target.

Conlon
for
Edwin L. Johnson
Director
Office of Pesticide Programs

cc: J.M. Conlon
W. Wells

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 23 1982

JUN 24 REC'D

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Honorable Andy Ireland
House of Representatives
Washington, D. C. 20515

Dear Mr. Ireland:

Thank you for your letters of May 27, 1982, to Administrator Gorsuch and me concerning the Agency's pending decision on ethylene dibromide (EDB).

We recognize that it is very important to your state's citrus exporters that EDB not be phased out unless there is an alternative available which is effective and acceptable to Japan. Accordingly, the phase-out date of mid-1983 originally proposed will be carefully re-evaluated.

We also recognize the importance of sharing information and coordinating our activities with the Occupational Safety and Health Administration (OSHA), which is considering regulatory action on EDB as well. My staff meets with OSHA regularly, and on occasion I have personally participated. In addition, we keep the Japanese government informed of the status of the EDB decision.

Knowing the importance of this matter to Florida, I will be glad to meet with you and Senators Chiles and Hawkins soon.

Sincerely yours,

John A Todhunter

John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides
and Toxic Substances

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 13 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Edwin L. Johnson
Director
Office of Pesticide Programs (TS-766)

SUBJECT: Report of EDB in Irrigation Wells

I have recently heard reports that a groundwater monitoring study underway in Georgia has detected ethylene dibromide (EDB) in two adjacent irrigation wells. I would like you to follow up on these reports to determine the significance of the study results and how the study relates to the EDB groundwater study underway in California.

I have serious concerns about EDB contamination of groundwater and I expect you will take whatever action is necessary to determine the extent, or absence, of such contamination.

John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides
and Toxic Substances

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 9 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Report of EDB in Georgia Irrigation Wells: Summary of Meeting with Great Lakes Chemical Company

FROM: Paul R. Lapsley, Chief
Chemical Review Branch #4
Special Pesticide Review Division (TS-791)

Paul Lapsley

TO: File

On July 7, 1982, Joe Panetta, Bill Miller (RD) and I met with Mr. Vern White of Great Lakes Chemical Company to discuss a report idicating that two Georgia irrigation wells are contaminated with ethylene dibromide (EDB).

The subject of the meeting was a June 15, 1982 letter from Dow Chemical company (attached) which stated that two of three sampled irrigation wells near Donalsonville, Ga. had EDB levels of 100 and 33 ppb, respectively. Although representatives of Dow Chemical were invited to the meeting, they did not attend.

Mr. White told us that the initial sampling and analsyses were conducted by Ms. Luz Marti, of USDA in Georgia, as part of her graduate work at Florida State University. Mrs. Marti's results were confirmed by two independent sampling programs, one conducted by Dow and a later one conducted by Great Lakes Chemical Company.

Mr. White explained that, although he knew from a recent site visit in response to the initial monitoring results that EDB was used in the vicinity of the wells, he did not have precise information regarding the frequency or rates of application. However, the farm consultant who has advised the local farmers regarding pesticide application over the last 8 years has promised to send Mr. White his field records. These records may provide precise information regarding the number of EDB applications per year and the volume per acre. Based on information from his site visit, Mr. White does not believe the contamination of the wells is a resullt of a spill or related to EDB mixing operations.

Mr. White expressed concern over any EDB contamination of groundwater that could be detected in the part per billion range; even 3-10 ppb levels concerned him. He believes that contamination levels in the part per trillion range could be acceptable. His position is contrary to the Dow position, stated in their June 15 letter, that contamination levels of 100 ppb represent "an adequate margin of safety."

Mr. White promised to send a letter volunteering to conduct groundwater monitoring studies after suitable protocols had been worked out with EPA. I expect that Great Lakes' willingness to undertake the cost of the studies will depend on the scope of the studies and the willingness of other registrants, such as Dow, to share in the cost.

I later spoke with Carolyn Offut (HED), who was unable to attend the meeting, and explained that I would be requesting HED assistance in designing the studies once I received the letter from Great Lakes.

Attachment

cc: S. Cohen
W. Dickinson
E. Johnson
C. Offut
J. Panetta

THE DOW CHEMICAL COMPANY

MIDLAND, MICHIGAN 48640

P.O. Box 1706

ASAP

6/2

June 15, 1982

Mr. William H. Miller
Product Manager (16)
Registration Divison (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Waterside Mall, East Tower
Washington, D.C. 20460

Subject: Ethylene Dibromide (EDB) in Irrigation Well Water

Dear Mr. Miller:

This letter is to reiterate and formalize the information that I conveyed to you in our telephone conversation on June 14, 1982, concerning the presence of EDB in irrigation well water in Georgia.

Initially, the possible presence of EDB in the irrigation well water was conveyed to us by Florida State University. The latter had received three water samples taken from irrigation wells near Donalsonville, GA, in September, 1981, for analyses. Subsequent analyses of the samples by Florida State University in April, 1982, indicated the possibility of concentrations of EDB in one of the wells to be in the range of 100 parts per billion (ppb).

After being informed of these findings in May, 1982, we obtained samples from the same three wells and conducted our own analyses. The results were as follows:

Irrigation Well/Depth (ft.)	EDB (ppb)*
#1/60-70	100
#2/60-70	33
#3/125	ND**

*Average of two samples.
**Not detected using an analytical method sensitive to 0.2 ppb.

To the best of our knowledge, the three wells sampled are irrigation wells not intended for use as a source of drinking water.

Using inhalation data from the most recent NCI study[a] which reported the lowest dose of EDB to elicit a carcinogenic response in rodents to be 10 ppm in air, a continuous daily equivalent ingestion dose of

[a] National Toxicology Program. 1982. Carcinogenesis Bioassay of 1,2-Dibromethane (CAS No. 106-93-4) in F344 Rats and B6C3F$_1$ Mice (Inhalation Study). NTP-80-28. NIH Publication No. 82-1766. NTP Technical Series Report No. 210. Research Triangle Park, NC 27709. March.

4.5 mg EDB/kg of body weight was calculated. These calculations assumed 100% absorption of EDB, a respiratory minute volume of 0.075 liters/minute for a 330 gm rat (0.330 kg rat), and a concentration of 10 ppm EDB equivalent to 0.077 mg/liter:

1) 0.075 liters/minute x 60 minutes/hour = 4.5 liters/hour
4.5 liters/hour x 6 hours/day = 27 liters/day
27 liters/day x 5 days/week = 135 liters/week
135 liters/week x 0.077 mg/liter = 10.4 mg/week

2) $$\frac{\text{10.4 mg EDB/week}}{\text{7 days/week}} = \text{1.5 mg EDB/day per rat}$$

3) $$\frac{\text{1.5 mg EDB/day/rat}}{\text{0.330 kg rat}} = \text{4.5 mg EDB/kg body weight per day}$$ equates with the inhalation of 10 ppm EDB in rats.

Assuming a "worst case" situation, the presence of 100 ppb EDB in 2 liters of water consumed per day by a 70 kg person equates to an intake level of 3 micrograms EDB/kg body weight per day. Comparison of the lowest daily dose level eliciting a carcinogenic response in the rodent studies with the calculated "worst-case" situation for humans described above indicates a 1500-fold difference between the two. In our best judgement, this difference represents an adequate margin of safety in regard to any inadvertent oral human consumption of water from irrigation wells containing as much as 100 ppb EDB.

If you have any questions about the above information, please call me.

Sincerely,

Margaret L. Wulf

(Miss) Margaret L. Wulf
Regulatory Response Leader
Regulatory & Legislative Issues
Health & Environmental Sciences
(517) 636-6376

jan

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21

July 15, 1982

Dr. John Todhunter
Assistant Administrator for
Pesticides
Environmental Protection Agency
Washington, D.C. 20460

Dear John:

I want to thank you for taking the time to come up to the Hill this afternoon to meet with Sen. Chiles and myself, and the representatives from OSHA and USDA. This is the sort of liaison on the EDB question which will be critical in the days ahead as we work together toward a sensible solution to this situation.

I particularly appreciated your assurances that there is no "rush" to ban EDB, either in 1983 or 1985, but that this is just one of several staff options which have been discussed. Further, it was reassuring to hear that your principal motivation in airing even this option is to "get the attention" of those states which are not cooperating as well as Florida in the actual use of EDB. Finally, I was very pleased to hear that EPA's ultimate goal in all of this is to help develop levels of exposure for applicators which are truly safe.

Moving to the implications of any rule-making on EDB, I welcome your response to Senator Chiles' remarks about the importance of continuity and the need to avoid giving Japan any excuse to decline further shipments of Florida grapefruit.

Finally, I appreciate your acceptance of Senator Chiles' request that we meet again, or on a regular basis, with the OSHA and USDA representatives as well, so that we are all kept informed on the situation regarding EDB. Until or unless a safe alternative is found, the importance of EDB -- safely used -- to the agricultural economy of Florida and the nation is obvious, and EPA will play a critical role in safeguarding all of these concerns.

Many thanks again for participating in today's useful meeting.

Sincerely,

API:cn
CC: The Hon. Ann Gorsuch
The Hon. Lawton Chiles
The Hon. John Block

PLEASE RESPOND TO: ☑ WASHINGTON ☐ WINTER HAVEN ☐ BRADENTON ☐ SARASOTA ☐ LAKELAND

MEMORANDUM

TO: Mr. Alvin Alm
Deputy Administrator, Environmental Protection Agency

FROM: Sunkist Growers, Inc.

DATE: September 8, 1983

SUBJECT: Ethylene Dibromide ("EDB")

It is understood that your Agency is currently developing a final Position Document regarding the registration of EDB. Of particular concern is its use as a post harvest quarantine treatment. As you may be aware, citrus may be required to be fumigated with EDB prior to shipment in domestic and foreign commerce to prevent the spread of various plant pests such as the Mediterranean fruit fly. Without such treatment the citrus cannot be marketed.

It has been reported that strong consideration is being given to cancelling the registration of EDB for quarantine use effective in 1984 or 1985. Such an action will have a severe impact on the United States citrus industry in both domestic and international markets. It is believed that alternatives to cancellation can be implemented consistent with the mission of your Agency to protect human health and the environment.

It is recognized that the pesticide registration of EDB has been under review for several years. Of particular concern have been risk to workers handling EDB and EDB-treated commodities (occupational exposure) and risk to consumers of EDB-treated commodities (dietary exposure). Regarding occupational exposure, the citrus industry, in cooperation with various federal and state agencies and labor groups, developed a series of work practices to reduce such exposure to levels acceptable to the various regulating agencies.

A similar cooperative effort has commenced on the dietary exposure problem. While legitimate questions could have been raised with the preliminary risk assessment performed by your Agency, namely whether it is a realistic or reliable predictor of the effects of dietary exposure to EDB, it was recognized that efforts had to be directed at identifying what measures could be taken to reduce residue levels. In that regard, an intensive research effort was commenced in June of 1983 involving the U.S. Department of Agriculture and the Florida citrus industry. Only a limited amount of fruit was

Heron, Burchette, Ruckert & Rothwell
Suite 420
1200 New Hampshire Avenue, N.W.
Washington, D.C.

available for the research effort because the research period (June-August) came at the end of the citrus season. However, certain measures were examined to determine their impact on reducing residue levels. These included, for example, reducing the dosage required for treatment, making time/temperature adjustments, reviewing the effect of holding treated fruit, reviewing packing container material and examining ventillation procedures. At the same time, research continued into possible alternative treatments to EDB. These included other chemical treatments, cold treatment, and irradiation treatment. However, it must be stressed that currently, there is no available alternative quarantine treatment to EDB.

The data from the aforementioned cooperative research effort is being assembled and should be submitted to your Agency in the next several weeks. The preliminary data identifies the positive steps that can be taken to reduce dietary exposure. It also shows a critical need for additional work to be done. The cooperative research effort must continue.

It is hoped that in lieu of cancellation, your Agency, in conjunction with the U.S. Department of Agriculture, industry representatives, and any other interested party could develop a risk reduction protocol identifying additional risk reduction measures to be reviewed and, if successful, implemented to reduce dietary exposure. It would be expected that such effort would include establishing target residue levels which could be lowered over a two to three year period.

In view of the significant adverse economic consequences that will result from cancellation of EDB for quarantine purposes, it is urged that all other approaches such as those set out above be fully exhausted prior to any final decision. If there is any way to continue the quarantine use of EDB without causing an unreasonable adverse impact on man or the environment, it should be utilized.

Very truly yours,

Edward M. Ruckert

Millers' National Federation
500 Maryland Avenue, S.W., Suite 305
Washington, D.C. 20024 202-484-2200

[illegible]

Ex 22

November 10, 1982

TO: MEMBERS OF THE TECHNICAL ADVISORY COMMITTEE

William Mailhot, Chairman, General Mills, Inc.
F. W. Adler, The Pillsbury Company
L. Argir, International Multifoods Corp.
Jack Burkhalter, Cargill, Inc.
Robert S. Clark, Scott's Auburn Mills, Inc.
T. Hobelheinrich, ConAgra, Inc.
Khalil Mansour, The Mennel Milling Company
L. L. Warren, ADM Milling Company

voluntarily stopped using EDB

[illegible]

FROM: Tom Klevay, Director of Technical Affairs Tom

SUBJECT: NOVEMBER 9 MEETING WITH EPA ON ETHYLENE DIBROMIDE

Bill Mailhot and Darrell Jones of General Mills, and I met with Dr. John Todhunter, Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency, to discuss the status of the RPAR of ethylene dibromide. The work on EDB is being completed and a final announcement will likely be made by the end of the year. It appears that the prospects for the continued use of ethylene dibromide as a spot fumigant are good.

Enclosed is some additional information supplied to Dr. Todhunter at our meeting.

Enclosure

TJK:lar

Participants at Meeting
Wells
Hill
Conlon
2: Spot fumigation

National Association of the Flour Milling Industry

Natural Resources Defense Council, Inc.
25 KEARNY STREET
SAN FRANCISCO, CALIFORNIA 94108
415 421-6561

Washington Office
1725 I STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20006
202 223-8210

New York Office
122 EAST 42ND STREET
NEW YORK, N.Y. 10168
212 949-0049

January 19, 1984

VIA OVERNIGHT COURIER

William D. Ruckelshaus, Administrator
United States Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Re: Ethylene Dibromide (EDB)

Dear Mr. Ruckelshaus:

We are writing on behalf of the Natural Resources Defense Council, Inc., American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), Consumers Union of U.S., Inc. and California Agrarian Action Project to urge that you act swiftly and decisively to protect American consumers from further exposure to ethylene dibromide (EDB) in their food supply. We are utilizing these informal means in order, if at all possible, to avoid litigation during this emergency. However, appropriate legal relief will be sought should the Agency fail or refuse to act in conformity with responsibilities established by the Food, Drug and Cosmetic Act and Federal Insecticide, Fungicide and Rodenticide Act.

As you are aware, tests conducted by several states including Florida, Texas and California have discovered residue concentrations of EDB in a wide variety of grain products and other foods such as flour, cake mixes, cornmeal, oranges and other fresh citrus. In light of this public exposure to "the most cancer-causing chemical the Agency has tested," (Washington Post, December 26, 1983), we strongly urge the following steps be taken by the federal government to protect the American public:

1. Issue an emergency suspension of the registration of EDB under § 6(c) of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as a grain (wheat, rice, barley, buckwheat, corn, popcorn, oats, rye and grain sorghum) or citrus fumigant, so that EDB can no longer be sold for these purposes, and issue a "stop use" order under § 13 of FIFRA, so that present stocks of EDB in the hands of users can no longer be applied.

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Summary Rationale: The amount of actual residues of EDB being found in finished food products throughout the nation provides more than ample evidence that its continued use for fumigation of grain, citrus and other products presents an imminent health hazard justifying emergency suspension. The continued exposure of food products to a chemical that now appears quite clearly to find its way pervasively into the human diet is plainly unacceptable. EPA's cancellation order of September has been stayed by industry objections. Based on past experience, it will take two or more years to effectuate the proposed cancellation thereby allowing the continued manufacture, sale and use of EDB on food. It is crucial that no further contamination of the nation's food supply be permitted.

2. Institute a comprehensive testing program of both raw agriculture and grain products and finished food (i.e., cooked products or other food ready for human consumption) to determine the presence of EDB residues in all applicable products in the chain of commerce. Conduct tests, within thirty days and subject to independent peer review, ascertaining the extent to which residues in raw grain products are reduced or eliminated through aeration, processing or cooking by consumers. Utilize such independent test results in estabishing tolerances effective to ensure no further residue levels will occur in products consumed by the public.

Summary Rationale: The information gained from this comprehensive testing program is essential for EPA to assess the true extent of risk from EDB exposure to the public. Without this test data, the Agency will be unable to establish intelligent regulations to protect the public health. Such test results must be subjected to independent peer review in order to determine that the scientific procedures used and the conclusions drawn were valid.

3. Immediately rescind the 1956 exemption granted for EDB from the federal residue tolerance requirements of the Food, Drug and Cosmetic Act and issue a notice of proposed rulemaking under § 408 of the Act establishing tolerances for EDB in grain, citrus and other appropriate commodities. In order for such tolerances to be "safe" as mandated by law, they should be set to ensure that no residues of EDB will result in finished

food products ready for human consumption. In the case of animal feed or fodder treated with EDB, the tolerances set should ensure tnat residues will not occur in milk, meat, poultry or other end products. Pending establishment of a safe tolerance, EPA in conjunction with the Food and Drug Administration should establish federal "action levels" at levels sufficient to ensure that finished foods consumed by the public are free of this serious carcinogen.

Summary Rationale: In 1980, EPA concluded that EDB was a "potent animal carcinogen and a probable human carcinogen." The chemical also was found to cause heritable genetic mutations and a host of reproductive effects including testicular atrophy, reduced sperm count and sterility. Immediate cancellation was recommended because "human exposure to EDB poses substantial risks to the public health." This finding followed earlier 1974 and 1975 reports by the National Cancer Institute and EPA's own Carcinogen Assessment Group that "there is strong evidence that EDB is likely to be carcinogenic to man." (Position Document 2/3, hereafter "PD 2/3," at 8)

In September, 1983, the Agency's final determination on EDB called for cancellation of grain fumigation based upon an estimated risk of 3.3 increased cases of cancer per 1,000 Americans, or roughly three-quarter million Americans, resulting from a lifetime of daily dietary exposure to 31 ppb of EDB residues from bulk fumigations of grain products. This estimate of the lifetime cancer risk does not consider additional dietary exposure to EDB from spot fumigation of grain milling machinery, fumigation of fruit, contamination of vegetables from preplant soil fumigation or drinking water contamination. In comparison, preliminary reports indicate residues in grain products up to 1,700 ppb in California, 750 ppb in Florida and 650 ppb in Texas. Residues in oranges tested in California have been found at 1,420 ppb in the pulp and 7,600 ppb in the peel, prior to that state's recent embargo of out-of-state fruit. Therefore, the actual lifetime cancer risk to consumers may be significantly greater even than that estimated by EPA.

4. Immediately rescind the tolerance of one part per billion set on March 3, 1981 for EDB in soybeans.

Summary Rationale: To our knowledge, the only formal tolerance set for EDB was in 1981 for its use on soybeans. According to an EPA memorandum from Roger Gardner, Toxicologist, EPA Hazard Evaluation Division, to William Miller, Registration Division, February 27, 1981, EPA toxicologists believed that the one ppb tolerance request should have been denied because it would pose an unacceptable cancer risk and, among other things, failed to take sufficiently into account the use of soybeans for infant formula. The tolerance apparently was set without the concurrence of EPA's toxicologists.

5. Initiate an immediate investigation and report to the American public on:

   a) Why, throughout a six year RPAR and irrespective of actual knowledge by the Agency since at least February, 1981 that EDB residues were resulting in finished food products, a 1956 exemption from the tolerance requirements of the Food, Drug and Cosmetic Act was left in effect.

   (b) Why, irrespective of scientific knowledge as early as 1974 that EDB was a potent carcinogen, and an Agency decision in 1980 that its use for grain fumigation should be immediately suspended, it nonetheless took EPA nearly ten years to adopt a final regulatory position on this dangerous chemical. Moreover, that eventual action, with the exception of soil fumigation, permits use of EDB for the several more years during administrative hearings.

Effective and legally required action by EPA will not be without financial costs to the reluctant food industries but we are dealing here with the risk of increased cancer and other chronic health effects in the general population. Further, the extent of this financial impact is uncertain for several reasons.

First, according to EPA and USDA decision documents, only two percent of the nation's grain has been treated with EDB. (PD 2/3 at 299; PD 4 at 88) Second, aeration, rotating new and old grain stocks and other approaches may be used to significantly reduce residues in raw grain. Thirdly, according to statements by EPA representatives, EDB residues in finished foods may be largely reduced or eliminated by food processing and cooking. Finally, should contamination of grain prove extensive and not subject to adequate reduction, a system of incrementally reduced tolerances over a brief period of time may be necessary while this dangerous chemical is purged from the food chain.

We believe the above regulatory actions are compelled both by public health considerations and settled federal law, placing on the Administrator a heavy burden of ensuring that residues of any pesticide chemical in food are "safe" for human consumption. These responsibilities are vested in the federal government. They cannot be deferred or avoided by a suggested "safe" guideline or the delegation of responsibility to the individual states, as some press reports indicate is now being considered by EPA.

Regulatory History

A brief review of the tortured regulatory history of this chemical, summarizing the various conclusions of the National Cancer Institute, EPA's own scientists and the Scientific Advisory Panel, make the conclusion inescapable that all EDB use must be stopped immediately and tolerances established, the end result of which will prevent EDB residues in finished foods ready for human consumption.

EDB has been produced in the United States since the 1920s, primarily as a lead scavenger for gasoline. During the 1950s and 1960s, pesticide registrations for uses of EDB as a fumigant were granted, principally for preplant soil fumigation by injection, post-harvest commodity fumigation for grains, fruits and vegetables and fumigation of grain mills and milling machinery. In addition, emergency exemptions for EDB use on soybeans were granted in 1980. EPA estimates that about 340 to 360 million pounds of EDB are produced annually in the U.S. by four basic producers: Dow Chemical, Ethyl Corp., Great Lakes Chemical and PPG. Domestic pesticide usage comprises about 13 to 15 million pounds of annual U.S. production. Estimates of EDB that are exported are unavailable as confidential business information.

With one important exception, there are no tolerances for EDB per se in or on food commodities because of an incorrect assumption, based on data originally submitted in the 1950s, that it was not possible for EDB to leave residues in cooked or finished food. This conclusion relied on the hypothesis that EDB would either evaporate or convert to inorganic bromides. As a result, tolerances in processed food were set solely for inorganic bromides and not for EDB. Likewise, tolerances for raw agricultural commodities, such as citrus, were established solely for inorganic bromides because analytical techniques at that time could not detect entire molecules of EDB.

The NCI Cancer Alert and the 1980 Proposed Decision

On October 16, 1974, the National Cancer Institute (NCI) issued a cancer alert describing a preliminary finding that EDB is a carcinogen. On July 14, 1975, the Environmental Defense Fund petitioned the Agency to investigate EDB on a priority basis. In November, 1975, a final NCI study showed EDB to be carcinogenic in both sexes of rats and mice. EDF amended and renewed its petition in 1976 and 1977. Additional studies showed EDB to be mutagenic (i.e., heritable genetic mutations) and capable of producing adverse reproductive effects (i.e., sterility). Three years after the initial NCI study, in September 1977, EPA's Carcinogen Assessment Group issued a preliminary risk assessment which stated: "There is strong evidence that EDB is likely to be carcinogenic to man." (PD 2/3 at 8) Finally, in December 1977, the Agency issued its first notice of "RPAR" creating a rebuttable presumption that EDB presented a health hazard.

During the RPAR, the Agency granted extensions of time and then received 105 rebuttal submissions. In 1979, DBCP, a chemical closely resembling EDB in its makeup, was cancelled by the Agency. Several states applied for -- and received -- special exemptions from the normal requirements of FIFRA to allow EDB to be used as a replacement for DBCP.

In issuing its RPAR notice, the Agency relied upon data showing a significant increase in the incidence of stomach cancer (gastric carcinomas) in both sexes of rats and mice, and metastases (malignant tumors) were reported. Significant increases in tumors of the spleen, mammary and adrenal glands and other tissues also were found. Efforts by registrants to rebut these findings were uniformly rejected. The Agency concluded "that the animal data provide substantial evidence that EDB is a likely carcinogen for humans." (PD 2/3 at 17)

EPA also evaluated EDB studies to determine its mutagenicity. The Agency concluded that mutagenic risk was demonstrated for all registrations of pesticide products containing EDB. Again, industry objected, but their rebuttal evidence was uniformly rejected. (Id. at 21) Additional studies were found to add support to the Agency position that EDB induces mutagenic effects and causes chromosome damage. The EPA concluded that "EDB is a potent mutagen" and "sufficient evidence exists to indicate EDB presents a potential mutagenic risk for humans...." (Id. at 21, 23)

Finally, EPA determined that EDB was capable of causing reproductive effects including reduced sperm production and sperm mobility and abnormal sperm structure in a variety of animals (bulls, rats and mice) and atrophy of the testicles and prostate. The Agency concluded that the presumption that EDB causes reproductive disorders had not been rebutted and that there "is not an ample margin of safety from adverse reproductive effects for humans exposed as a result of the current pesticidal use practices of EDB." (Id. at 30)

Qualified Agency scientists and outside consultants then reached the following conclusions regarding the hazards of EDB and the need for regulatory action:

> Based on the accumulation of evidence, the Agency considers EDB to be a potent animal carcinogen and a probable human carcinogen. Because the pesticidal uses of EDB result in human exposure during application, through contamination of some foods during application, and during transport of treated commodities, the Agency concludes that EDB poses a risk of cancer to humans. The Agency also concludes that EDB causes reproductive disorders in bulls, rats and chickens, suggesting that repeated exposure to EDB may cause reproductive disorders in humans. Finally, the Agency concludes that adequate multitest evidence exists to demonstrate that EDB also causes mutagenic effects in several organisms. This evidence indicates that exposure to EDB poses a potential risk of genetic damage to man. Collectively, these three conclusions confirm qualitatively that human exposure to EDB poses substantial risks to the public health.

Id. at 95.

The Scientific Advisory Panel Decision

On April 22, 1981, the EPA Scientific Advisory Panel presented its views on EDB. The panel first found that "EDB is a carcinogen for multiple animal species,...is a potent mutagen producing point (gene) mutation, chromosomal aberration and primary DNA damage...[and] has been demonstrated to produce adverse reproductive effects in several species." (Report of Scientific Advisory Panel Recommendation, April 22, 1981 at 3) While urging that citrus fumigation continue to be permitted because of the absence of proven alternatives, with regard to grain fumigation, the Panel concluded as follows:

> The Panel wishes to make a clear distinction between the apparent hazards of citrus and grain fumigation insofar as human dietary factors are concerned, and thus does not concur with the Agency's proposal to cancel the use of EDB on citrus. As regards stored grain fumigation and spot fumigation of grain milling machinery, the Panel wishes to express its great concern over the possible presence of EDB residues in finished bakery products. The evidence is far from solid, but because of the extremely large population potentially at risk the problem demands resolution. Therefore, the Panel concurs with the EPA proposal to cancel stored grain fumigation and spot fumigation of grain milling machinery uses until such time as convincing evidence exists that such uses present little or no hazard to consumers of bakery products.

Id.

In large measure for political, not health or scientific reason, the 1980 proposed cancellation of EDB was not adopted for nearly three years.

The EPA Position Document 4, September 27, 1983

Position Document 4 (hereafter "PD 4") presented the Agency's final determination regarding EDB. Released on September 27, 1983, it announced the immediate discontinuance of EDB as a soil fumigant as a result of previously unknown leaching of the chemical to groundwater and resultant contamination of human drinking water supplies. The Agency issued an emergency suspension order which was immediately effective in prohibiting the continued use of EDB for this purpose.

In addition, EDB was cancelled on a non-emergency basis for bulk fumigation of grain and spot fumigation of grain mills irrespective of a finding by the Agency that these uses "pose[d] a significant dietary cancer risk to the general public and high risks to applicators and mill workers." The Agency declined to determine that emergency cancellation was necessary due to an imminent health hazard in the absence of "additional information" still to be gathered. This additional information was necessary more than nine years after the National Cancer Institute issued an alert establishing EDB to be a carcinogen. (PD 4 at ii)

Finally, EPA cancelled the use of EDB as a fumigant for citrus, tropical fruits, certain other commodities, again on a non-emergency basis and with an effective date delayed until September 1, 1984. This result was irrespective of an EPA finding that the use of EDB for these purposes "poses substantial risks to both occupationally exposed workers and to the general public." The non-emergency and delayed basis of the decision was predicated upon the need of allowing the industry "adequate time" to change to alternative means of fruit fly disinfestation. Lastly, the Agency permitted the continued use of EDB for domestic termite control because there was "no data...available which demonstrate that these exposures are significant." (Id. at iii)

Dietary Exposure

Residues of EDB may enter the human diet as a result of a variety of EDB uses including pre-plant soil fumigation resulting in drinking water contamination, post-harvest fumigation of grains and grain products, fumigation of grain mills, mill machinery and handling equipment (including transportation equipment), and post-harvest fumigation of fruits and vegetables. The principal grains for which EDB is registered as a fumigant are wheat and rice; wheat comprises the largest portion of the human diet. Human dietary exposure also can result from the use of EDB on corn, barley, sorghum, rye and oats which are used for livestock feed and such products as corn oil, cornmeal, cereals and the like. These uses can result in contamination of the human diet through residues in meat, milk and other products. According to EPA, in the past no data existed on such residues due to a lack of testing of such "secondary contamination." (PD 2/3 at 34).

In recommending cancellation of EDB, first in 1980 and finally in 1983, the agency performed a reevaluation of the total "dietary burden" of EDB with respect to post-harvest grain uses. In the 1980 review, it was estimated that the "probable" residue level of EDB in wheat bread derived from grain fumigated after harvest with EDB would be 0.07 ppb. It also was estimated that the "realistic worst case level" which assumed that grain would be treated at the maximum rate, not mixed with untreated wheat, and minimum commercial transit times would be 31 ppb. Another estimate using a "mass balance" approach yielded a theoretical contamination level of 87 ppb.

Very truly yours,

Albert H. Meyerhoff

Albert H. Meyerhoff
Jacqueline Warren
Lawrie Mott
Natural Resources Defense Council,

Stephen P. Berzon /s

Laurence Gold
Stephen P. Berzon
American Federation of Labor-
Congress of Industrial
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Governor Bob Graham
Governor Mark White

Following that analysis, the result of an investigation of actual residues in wheat flour in biscuits was published in February, 1981. All but one of 24 flour samples contained detectable levels of EDB (more than 0.5 ppb). The reported levels in flour ranged from 0 to 4200 ppb. Twenty of 22 biscuit samples baked from the flour also contained detectable levels ranging from 0 to 260 ppb and averaging 35.7 ppb. Based upon these actual test figures, the Agency, in its PD 4, concluded that "the realistic worst case level is the more appropriate estimate for the actual dietary burden." PD 4 then concluded as follows:

> The Agency is continuing to monitor for residues of EDB in grain, flour and finished baked goods. This monitoring is being undertaken in coordinated interagency efforts with USDA and the Food and Drug Administration. In addition to flour and baked goods, milk and meats including beef, poultry and pork are being sampled. The Agency will continue to evaluate these data to establish a more complete understanding of the extent of hazard to public health resulting from fumigation of stored grains and spot fumigation of grain milling machinery. If the extent of the hazard posed by either or both of these uses of EDB becomes more clearly delineated and defensible, the Agency will consider emergency suspensions for these uses.

Id at 58.

In the 1983 decision, the agency's Carcinogen Assessment Group also revised the 1980 estimates of cancer risks associated with EDB residues in the diet. The estimate of bulk grain dietary burden was increased significantly:

> ...and therefore, the risks for the average U.S. consumer from this use also increases signficantly. The estimate for additional cancer risk die [sic] to bulk grain fumigation is now 3.3×10^{-3}. [3.3 increased cancers for each 1,000 consumers] This estimated risk from the bulk grain use constitutes a majority (approximately 85%) of the known dietary risks from EDB.

Id. at 70 (emphasis in original).

This estimate of 3.3 excess cancer cases in 1,000 consumers or approximately 750,000 Americans, after a lifetime of exposure to EDB comes from only one daily dietary source: 31 ppb of EDB in grain products that have been subject to bulk fumigation. The figure does not include the additional cancer risk from dietary exposure to EDB resulting from uses other than bulk fumigation, such as spot fumigation of grain milling equipment, fumigation of fruits and vegetables and preplant soil fumigation. This lifetime cancer risk estimate also does not consider exposure to EDB in drinking water. Recent findings of EDB at levels as high as 1700 ppb in grain products, 1,420 ppb in citrus, 5 ppb in carrots and 300 ppb in drinking water demonstrate that the lifetime cancer risk to Americans from dietary exposure to EDB may be substantially higher than EPA's estimates of 3.3 excess cancer cases per 1,000 consumers. Possible additional dietary burden based upon meat and milk contaminated by livestock fed with EDB-contaminated grains also was not factored in due to a lack of information.

The final EPA position document then concluded as follows:

> The Agency has determined that EDB is a potent animal carcinogen, a mutagen to a variety of plant and animal cells, and is capable of producing adverse reproductive effects in animals. EDB is potentially capable of producing these adverse health effects at measurable levels in the human diet,... The Agency has determined that no remedial changes can be made in the registration of EDB for most uses to avoid unreasonable adverse effects on human health.

Id. at 102.

Notice of Intent to Cancel

Following issuance of the PD 4, EPA issued a Notice of Intent to Cancel EDB. That document's discussion of dietary risk from EDB states the following:

> Everyone in the United States is potentially exposed to significant levels of EDB in his diet. EDB is found in grain products including cereals and bread, and in citrus and tropical fruit which has been fumigated with EDB.

> Although EDB has until recently never been detected in crops grown in soil which has been fumigated with EDB, residues have now been preliminarily reported in miniature carrots. EDB may still be present in other foods grown in treated soil at levels which are below the limit of detection of the best available analytical techniques.

"Notice of Intent to Cancel" at 20.

Hearings have been requested on the cancellation of the grain fumigation and spot treatment cancellations of EDB by BPI Corporation, Douglas Chemical Company, Vulcan Materials Company and others. Among the reasons for the hearing requests was "questionable accuracy of data on residues and baked food products." Hearings also have been requested to challenge cancellation of EDB for fumigation of soil, citrus and other crops.

The Notice of Cancellation prohibited any person from distributing, selling, offering for sale, holding for sale, shipping, delivering for shipment or receiving EDB. However, it provided that the "use of any product containing EDB which is not registered for such use at the time of such use is prohibited after September 1, 1984."

The Requirements of the Food, Drug and Cosmetic Act and Settled Case Law Require EPA to Protect the Public from Exposure to EDB in Their Food.

As the previous discussion indicates, EDB is a powerful carcinogen, producing a variety of tumors in laboratory animals -- and in as little as two weeks. To permit residues of this chemical to remain in American food, with the imprimature of the federal government would be both unprecedented and illegal. In the face of overwhelming evidence of the health risks presented, the failure of the Agency to cancel its use years ago, as well as leaving intact an "exemption" from federal tolerance requirements irrespective of actual residues in food, amount to serious government malfeasance. It is now incumbent on the Agency to act, effectively and expeditiously, to both regain the public trust and protect its health in this emergency.

Under the statutory mandate of the Food, Drug and Cosmetic Act, it is the duty of the Administrator to protect the consuming public from exposure to carcinogens and other chronic health hazards in their food supply. See, e.g., Environmental Defense Fund ("EDF") v. Ruckelshaus [DDT], 439 F.2d 584 (D.C. Cir. 1971); EDF v. HEW [DDT], 428 F.2d 1083 (D.C. Cir. 1970); EDF v. EPA [heptachlor and chlordane], 548 F.2d 998, 1005 (D.C. Cir. 1976)(cert. denied 431 U.S. 925 (1977); EDF v. EPA [aldrin and dieldrin] 510 F.2d 1292, 1302 (D.C. Cir. 1975); cf., EDF v. EPA, 598 F.2d 62, 88 (D.C. Cir. 1978). These cases discuss in detail the intent of Congress in enacting the Food, Drug and Cosmetic Act and investing in the federal government the responsibility of setting "safe" levels of chemicals consumed in human food. Likewise, applicable EPA regulations provide for a "zero" tolerance for pesticide residues where "the chemical is carcinogenic to or has other alarming physiological effects upon one or more species of the test animals used, when fed in the diet of such animals." 40 C.F.R. Part 108.5(b). Given the Agency's own findings that EDB is a potent animal carcinogen, "probable human carcinogen," and cause of genetic mutations and reproductive impairment, the agency's duty to set tolerances for EDB preventing contaminating of finished food products is clearly established.

The affirmative duty of the Administrator to prevent carcinogens in human food is probably best articulated in the landmark DDT case, EDF v. HEW. There, the U.S. Court of Appeals first noted that the legal and public policy considerations prohibiting known carcinogens in the food supply were historically well rooted. Thus, just prior to Thanksgiving 1959, The Department of Health, Education and Welfare seized much of the nation's cranberry crop because it contained residues of aminotriazole, a weed killer. In announcing the legal basis for this decision, in language directly applicable to the current EDB problem, then-HEW Secretary Arthur Flemming said the following:

> * * * Research has established the fact that the weed killer, aminotriazole, causes cancer in the thyroid of rats when it is contained in their diet.

> It is the Department's position that because such a chemical is unsafe, we cannot issue a regulation setting a tolerance for it when it causes cancer in man or animal.* * *
>
> This policy is basic in our food and drug law, and it was spelled out in the law itself when Congress recently passed the Food Additives Amendment. This included the following provision:
>
> [Delaney Amendment set out]
>
> In endorsing this language, we told Congress this policy was already in force under the pesticide chemicals law without the above-quoted language.

428 F.2d at 1090-91 (citation omitted emphasis in original)

The court then went on to note that when Flemming provided the Eisenhower Administration position to Congress supporting an extension of the Delaney anti-cancer Amendment, his testimony reaffirmed that the federal government already was legally bound to prevent carcinogenic pesticide residues in food:

> In his testimony, Secretary Flemming emphasized that scientifically there was no way to determine a "safe" level for a substance known to produce cancer in animals. Relying on this scientific finding, Flemming again told Congress that HEW would be required to apply the no-carcinogen policy even absent the explicit statutory command:
>
> "According to the advice of our scientists, the principle of the * * * anticancer (Delaney) proviso of the Food Additives Amendment reflects, basically, the current state of scientific knowledge, and we would therefore, except as noted below, feel constrained to apply the same principle even in the absence of this proviso, and we do in fact apply it in the administration of the Pesticide Chemicals Amendment which does not contain the proviso."

428 F.2d at 1091 (*citing* H.R. Rep. No. 1761, 86th Cong., 2d Sess., Appendix, 2 U.S. Code Cong. and Ad. News 2887, 2936 (1960))

The court then held that absent a scientific basis establishing a "safe" level of a carcinogen, under § 408, "it would obviously be impossible to meet the congressionally imposed burden of establishing the safety of a residue of such a pesticide." 428 F.2d at 1092. The full holding of the court, which binds the Administrator in the present EDB context, was as follows:

> Section 408 of the FDCA authorizes the Secretary of HEW to establish tolerances for pesticide residues on or in raw agricultural commodities "to the extent necessary to protect the public health." The section also authorizes the setting of a zero tolerance (no residue) level "if the scientific data before the Secretary does not justify the establishment of a greater tolerance." We need not pause to plumb the obvious ambiguities in this language since both Senate and House Committee Reports make the intended meaning of this section indisputably clear:
>
>> "Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide-chemical residue is safe from the standpoint of the food consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue."

Id. at 1091-92.

Beyond question, EDB is a potent carcinogen. In setting a tolerance, a continuing "burden" of proof remains with the pesticide producer to "establish the safety of such pesticide chemical residue." Id at 1092 and n. 9. No data before the agency has or can demonstrate that consumption by the American people of EDB in finished food products is "safe." To the contrary, the EDB scientific data base demonstrates the chemical is so hazardous to human health as to warrant cancellation.

Were the scientific data on EDB's carcinogenicity equivocal, a different result might be permissible. But it is not. It is a highly dangerous chemical. As the U.S. Court of Appeals recently recognized after citing several of the above pesticide cases, "[w]hen firm evidence establishes that a chemical is a carcinogen, statutes generally leave an administrator no alternative but to step in to protect the public." The court then went on to state:

> "Courts have traditionally recognized a special judicial interest in protecting the public health, particularly where 'the matter involved is as sensitive and fright-laden as cancer.' Where the harm envisaged is cancer, courts have recognized the need for action based upon lower standards of proof than otherwise applicable." [citation]
>
> * * *
>
> These cases demonstrate the inevitable tension attending regulation of carcinogens. Frequently, such regulations have severe economic impact....
>
> What scientists know about the causes of cancer is how limited is their knowledge. The record in this case demonstrates that it may take decades for human exposure to carcinogens to result in cancer; in the meantime, the case for inferring a cancer danger with respect to an incompletely understood substance is vigorously disputed. If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result.

EDF v. EPA, 598 F.2d 62, 88-89 (D.C. Cir. 1978).

Conclusion

The duty of EPA here is clear: to take action affording the consuming public the greatest possible protection from exposure to this cancer-causing poison. We believe the steps outlined above will accomplish that result.

Very truly yours,

Albert H. Meyerhoff /l

Albert H. Meyerhoff
Jacqueline Warren
Lawrie Mott
Natural Resources Defense Council,

Stephen P. Berzon /s

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Governor Bob Graham
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[From the Los Angeles Times, Feb. 1, 1984]

Memos Reveal Early Cancer Warnings on EDB, Efforts to "Soften" Agricultural Ban

(By Robert L. Jackson)

WASHINGTON.—Shortly before the Environmental Protection Agency slowed down proceedings to ban the cancer-causing pesticide EDB in 1981, a senior EPA official urged such a delay because he said it could enable the government to "soften" its action against industries using the deadly chemical, according to government memos obtained Tuesday by The Times.

A ban on EDB, considered the most powerful carcinogen yet identified, had been recommended by EPA's professional staff and legal procedures had been set in motion to halt its then-widespread use on citrus and grain crops throughout the United States. But the EPA official urged a delay because he said waiting for additional scientific data from industry could "allow a softening of our regulatory decision," the memos show.

In a memo on Dec. 24, 1981, Bill Wells, EPA's representative at the White House-citrus industry meetings said, "We should not push for an earlier resolution" of the dispute over federal standards for EDB because citrus growers had promised that lower residue levels would result from "improved transport, venting and storage procedures."

"This data is likely to allow a softening of our regulatory decision," Wells wrote. "If we push to a quick RPAR (EPD crackdown) we may not have as much leeway in softening the position."

Industry representatives opposed a ban on EDB because, they said, it posed no health hazard in the small amounts lingering in fruits and grain. EPA scientists and environmental groups urged a total ban because of the chemical's power and the fact that no safe exposure level for EDB had been established.

Proceedings to ban EDB were set in motion near the end of the Jimmy Carter Administration. The delay was urged during the first year of the Reagan Administration and an outright ban still has not been issued, even though EDB residues in food have become a subject of nationwide concern.

RECALLS WHITE HOUSE MEETING

The documents obtained by The Times show that the EPA failed to take prompt action on the chemical, ethylene dibromide, after a series of White House meetings with citrus industry representatives. The meetings were partly arranged by James H. Lake, a lobbyist who had been a key aid in President Reagan's 1980 election campaign.

Lake said Tuesday he recalls setting up only one White House meeting in late 1981, for an official of the Western Growers Assn. But, Lake said, "it could have been more." He said the association was concerned that federal officials might ban EDB or adopt strict EDB controls similar to action taken in September, 1981, by the California Division of Occupational Safety and Health, which had limited exposures for workers fumigating fruit or handling fumigated fruit to 130 parts per billion.

Lake, who is now communication director for Reagan's reelection committee, said he did not personally attend any White House meetings on EDB, leaving that role to his business associate, Edward M. Ruckert. The documents show Ruckert represented Western citrus growers including the California-Arizona Citrus League.

"I'm very comfortable with the role I played," Lake said in an interview. "People arrange opportunities every day for business groups to take their case to the government."

Jonathan Lash, an attorney for the Natural Resources Defense Council, on the other hand, said the environmental lobby is suing EPA on the ground that such meetings with growers about pesticide regulations must be public. All groups concerned with pesticide regulations must have an equal chance to present their views to the agency, Lash said.

John Todhunter, a former EPA official whose office dealth with EDB issues at that time, denied Lash's charges. Todhunter said he "didn't try to meet with anybody in particular" in considering pesticide issues, and that any material he recieved "went into the public rule-making record."

Wells, who wrote the memo urging a delay in acting on EDB, was one of Todhunter's chief assistants. Refering to meetings which EPA was then conducting with officials of the Agriculture Department and the Labor Department's Occupational

Safety and Health Administration, Wella said a public statement on the issue "would do nothing to help and would only serve to refocus attention on EDB."

A Wells memo from an earlier White House meeting on Oct. 21, 1981, reflected industry arguments that continued use of EDB as a fumigant was necessary to prevent the spread of Mediterranean fruit flies. Wells' memo indicated that industry representatives "want federal expertise brought to bear" and "want strong statement from federal government to reduce panic."

TELLS OF PANEL'S DISAGREEMENTS

Lake said the meetings with industry representatives took place at the White House to "transcent the bickering between different federal agencies" concerned with EDB regulation. Representing the White House at the meetings with industry officials was Dennis Praeger of the President's Office of Science and Technology, according to the memos.

Todhunter said EPA never had sought to slow down regulations of EDB to favor the citrus industry. The biggest delay, he said, was caused when numbers of EPA's outside science advisory panel disagreed over banning its use on citrus crops because some members believes that there was no workable alternative to combat the Medfly threat.

Todhunter resigned from the EPA last March 25 amid congressional investigations into EPA's toxic waste and pesticides programs.

The agency decided last September to ban all uses of the cancer causing chemical for soil treatment and to phase out its use on citrus fruits and raw grain. The current EPA administrator, William D. Ruckelshaus, is considering more drastic restrictions as evidence of EDB's health risks has mounted.

Senator **Durenberger**. I understand that one of the witnesses today has a serious time problem. He may have been the person responsible for our getting up early this morning, I don't know. But Dr. Gilles, who would have been our next witness, has agreed to hold off his testimony so we can call the panel of Mr. Sherwin Gardner, vice president, science and technology, Grocery Manufacturer's Association of America; and Norton Nelson, professor, Institute of Environmental Medicine, New York University Medical Center, New York, N.Y.

If I could call both of those gentlemen up, with the reminder of the 7-minute rule on oral testimony and pledge that without objection, your written statements will be made a part of the record.

We will ask Mr. Gardner to go first.

STATEMENT OF SHERWIN GARDNER, VICE PRESIDENT, SCIENCE AND TECHNOLOGY, GROCERY MANUFACTURERS OF AMERICA, ACCOMPANIED BY JOSEPH V. RODRICKS, TOXICOLOGIST

Mr. **Gardner**. Thank you, Mr. Chairman, and good morning. Accompanying me this morning is Dr. Joseph V. Rodricks, seated on my left, who is a nationally recognized toxicologist and a member of the Board of Toxicology and Environmental Health Hazards of the National Academy of Sciences. We appreciate the opportunity to appear here and share with you our views on the question of EDB residues in food made from grain.

Mr. Chairman, this hearing is very timely. During the next week the U.S. Environmental Protection Agency faces a number of important policy decisions regarding EDB. Since Congress and the press began to focus on EDB last fall, a great many questions have been raised. Consumers are confused, and several of our major international grain customers have expressed concern over the safety of grain-based products and raw agricultural commodities which may contain EDB residues.

Last October EPA announced that it would no longer permit the sale of EDB. A decision is expected next week.

The committee is correct in examining the ramifications of this decision. The food industry has cooperated fully with the Federal Government: the EPA, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture. We remain committed to insuring that the Nation's food supply remains the safest in the world. We have developed and shared an extensive technical report based on over 1,000 samples of raw grain, flour, product mixes, and foods eaten by the consumer from across the country.

We have received, since offering that report, about 1,000 additional data items and will share those with EPA as soon as we can assemble them.

We have retained the best scientific expertise available to assess if the public would be exposed to a significant risk by consuming products which may contain minute amounts of EDB over the next few years. Based on this hard scientific evidence, we have reached two important conclusions.

First, consumers should know that eating grain-based products which may contain minute amounts of EDB over the next few years presents no health hazard.

Second, while raw grains and product mixes may contain EDB residues, processing and cooking substantially reduce these residues to insignificant levels.

Following Florida's actions removing products from sale, GMA asked its member companies to conduct laboratory tests of grain and foods for EDB. Each participating GMA company carried out its own sampling and analysis program to develop data. Samples were taken at random from locations throughout the United States from existing stores of grain and flour. In addition, a variety of finished foods—bread, cookies, pasta, and others—were prepared in order to test the condition of foods as consumed.

Our objectives in conducting these tests were to obtain data that reflected the level of EDB residues in raw grain commodities, the effect of processing on EDB residues in the course of converting raw grain into flour, meal, and other grain products, and the effect of baking and other cooking techniques on EDB residues in foods produced from grain.

As I said, additional data are being generated and will be supplied to EPA. These data may modify the results just described.

The EDB level in products as consumed is particularly important as it serves as the basis for conducting a risk assessment. A valid risk assessment on the potential risks from exposure to EDB-treated grain products as consumed must be conducted before taking actions to remove products from the marketplace.

GMA has undertaken a risk assessment study of EDB in grain products and has provided a report on this study to the EPA. This report demonstrates that existing food products containing minute levels of EDB present no health hazard. The scientific evidence we believe does not support any action against grain products.

Mr. Chairman, I would like to offer for the record a copy of the report that we submitted to the Environmental Protection Agency.

Senator **Durenberger**. Without objection, we will make it a part of the file of this hearing.

Mr. GARDNER. I might note that all risk assessments require that certain assumptions be made. We believe that the use of EDB on grain will be discontinued. We understand that the use of EDB as a spot fumigant has generally ceased. We estimate that it would take approximately three years to use up the existing grain inventory. This estimate is included in our risk assessment. During this period, EDB residues will gradually be reduced until EDB is effectively removed from the food supply.

Taking into account the distribution of EDB in different types of grain products and their relative consumption in the diet, we estimate the current concentration of EDB in grain products to be 1.67 parts per billion. Over this 3-year period of our estimate, additional reductions will occur through natural dissipation of EDB. Therefore, the average level of EDB concentration in the total diet will be reduced to 0.033 parts per billion.

Using the Food and Drug Administration and Environmental Protection Agency accepted methodology, Dr. Rodricks has estimated for us the upper bound risk due to EDB consumption in grain products to be less than 1 in 4 million for children and less than 1 in 12 million in adults. These values are well within the range of risks generally considered to be insignificant.

Even if a longer phaseout period is assumed, to allow EPA's regulatory procedures to complete the cancellation proceedings, these risks would not materially change. For example, if a 5-year phaseout period is estimated, the risk figures become less than 1 in 2.4 million for children and less than 1 in 7.2 million for adults. These levels of risk are still insignificant and, as Dr. Rodricks can explain, are considerably less than the risk of eating two charcoal-broiled steaks per year or drinking chlorinated water from the supplies of certain metropolitan areas in this country.

Mr. Chairman, that concludes my statement, and Dr. Rodricks and I will be glad to respond to any questions the committee may have.

Senator DURENBERGER. Thank you very much. Dr. Rodricks, we appreciate your taking time to be here also.

Dr. Nelson, I understand you don't have prepared testimony. I wonder if you wouldn't take a little time and perhaps start with a little bit of your background in this area and then the subcommittee would very much appreciate hearing the testimony on what we heard earlier here from EPA and the general views on the subject as well.

STATEMENT OF DR. NORTON NELSON, PROFESSOR, INSTITUTE OF ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY MEDICAL CENTER

Mr. NELSON. I received an invitation to appear the day before yesterday when I was out of town and was back in my office, one of two offices, the one which did not have my sources, for only a few hours yesterday. I guess with the lateness of the request to appear, one may conclude I may not be the first choice here, but be that as it may, I am Norton Nelson, professor of environmental medicine at NYU Medical Center. For some 25 years I directed the Institute of Environmental Medicine and was Chairman of the Department of Environmental Medicine at the New York University Medical Center. The Institute, as I like to believe, is one of the leading centers of research and teaching in this field. A major concern of the Institute through the years of my direction and that of my successor has been cancer from external sources.

It has been my privilege, and duty, to serve on a series of national advisory committees relating to environmental cancer and health problems similar to this. Indeed, perhaps by coincidence, I served on an NCI Advisory Group during the first study on EDB. I was Chairman of the Board of Scientific Counselors of the National Toxicology Program until my term ended some months ago, during which time the inhalation study on EDB was conducted. One of the relevant studies was in fact done in our own Institute.

So I guess I would say that without being wholly informed in all of the details of these studies, my career has been closely related to these results.

There are now three different kinds of relevant studies on the carcinogenicity of EDB. Each one is decisively positive. I am talking about laboratory studies on animals. I think the point where one can argue as to the carcinogenicity of EDB for laboratory animals is long past. Indeed, the first NCI study was decisive, the inhalation studies were decisive, and the study that was done in our own Institute was also decisive.

If they have a fault, perhaps it is that the dose or, shall I say, response was so high in terms of tumor production that it makes it a little difficult to get the full picture of dose response relationships.

A key study was the study done by—do you wish a sort of short, nontechnical review of this?

Senator DURENBERGER. Yes.

Mr. NELSON. The first national cancer testing was done by gavage. If you please, somebody up there remind me to comment on the use of gavage as one form of oral dosage. It produced positive outcomes in mice and rats, male and female, at high levels of incidence.

A next important route of exposure were two inhalation studies, one done under NIOSH auspices and one done under the national toxicology program auspices. They were again decisive in producing cancer.

Another study that I referred to involved topical applications, that is skin application.

In all cases local tumors as well as remote tumors were found, and in general at high levels of incidence. All were histologically confirmed. There is no disagreement about these findings.

It is interesting, for example, in the study which was done in our Institute, involving as it did skin application did nevertheless, lead to tumors of the lung and tumors of the stomach. Characteristically, the findings were tumors of the stomach; which occurred with rather high frequency.

Now, in addition, under current concepts, for chemicals of this kind we now have a reasonably coherent understanding of the biological mechanisms by which they occur. That is by interaction with the material in the nucleus of the cell, DNA, in which irreparable damage occurs which, however, does not kill the cell. It is damage which is survivable but leads to altered growth, one form of which is cancer. So it has become important to know whether this compound or this general category of the compounds does in fact damage DNA. And the answer is yes, it does, and it does so in a variety of ways. This is clear, decisive, and has been repeated.

In addition to that, a next step after DNA damage has to do with mutations, as I have told you, which does not kill the cell but alters its growth pattern. This is customarily tested by a variety of laboratory procedures. Mutations have been produced explicitly in bacterial cells which have been found to be efficient predictors of cancer in animals and, indeed, in man mutagenicity has been demonstrated by this chemical in mammalian cells.

I guess I would just simply summarize this laboratory work by saying that the data are not in dispute insofar as carcinogenicity for rodents is concerned. Now we are all interested in the carcinogenicity for humans and not for the rat. Unfortunately, there are no epidemiological studies of sufficient consequence to answer this question for man. There are just one or two. They are technically either too small or otherwise limited so that they cannot give us any helpful information.

Now we have in this country, and throughout the industrialized world accepted the position that we cannot afford to wait until we have cancer victims dead before we take steps to control the potential carcinogen for man.

That being the case, and inasmuch as we are dealing with clearly a potent carcinogen for mammals, and we are all living in that realm of biology, the presumption must be made that it is potentially carcinogenic for man. It doesn't prove it is carcinogenic for man, but it must be regarded as potentially carcinogenic for man.

The well-known and well-respected International Agency for Cancer Research in Lyon, France, which I have worked with on many occasions, state the following, as a routine part of their final evaluation, that an agent for which there has been found to be sufficient information as carcinogenic must be regarded for practical purposes as potentially carcinogenic for man. IARC, the acronym for this agency, has twice reviewed EDB, once in 1977 and once in a supplement in 1982. In each instance they have concluded animal data are sufficient to demonstrate the carcinogenicity of EDB.

They also investigated the one most eligible study on man and concluded it is inadequate because of the size of the group to give decisive answers on carcinogenicity for man.

I think that really is enough to be said about this chemical. I would like to perhaps make a few comments about some criticisms that I know have been put forward on gavage as opposed to diet incorporation. Gavage may not be the best way to study carcinogenicity, but it has some advantages in terms of efficiency and in terms of avoiding inhalation of a powdered diet.

For example, in dioxin, gavage studies produced the expected cancers, and dietary studies produced rather comparable tumors. However, diet studies also produced lung cancer probably, or perhaps, through inhalation of the dust of the diet.

A comparable chemical, DBCP, has been studied by both gavage and diet incorporation; very similar outcomes were observed.

I think, sir, that's my summary, I will answer questions, if I can.

Senator **Durenberger**. Very good. I thank you very much for your testimony.

Mr. Gardner, your risk assessment is predicated on an assumption, at least I am told from the reading of the statement, that all EDB uses on stored grain and fumigation machinery have already ceased. I am curious to know whether you are confident that that is a fact. Our research indicates that there is still quite a few small mills using EDB and that there is at least probably a fair amount of on-farm use continuing as well.

Mr. **Gardner**. Senator, our assessment of risk does not assume that all use has ceased. Our assessment assumes that a considerable amount of usage has stopped but that the important point to make is that EPA has already ordered the end to further use as a fumigant, setting the regulatory mechanism in motion, and that setting that in motion will result in its removal, and that a 3-year period is what we could look forward to as a reasonable estimate for concluding that period. And again considering that use has stopped in a large number of instances, that is the basis for our risk assessment.

Senator **Durenberger**. So what you are saying to us then is that at the end of 3 years, if everything closes down, then we can rely on the findings of your assessment. In the interim period you might assess the situation somewhat differently.

Mr. **Gardner**. That is correct.

Senator **Durenberger**. The risk situation.

Mr. **Gardner**. That is correct.

Senator **Durenberger**. Would you support an emergency suspension order to insure that the assumptions of your risk assessment are met? Obviously I know a number of your larger members. They are located in my State. They are among the people I represent. One of them, the Pillsbury Co., has written to the Administrator of EPA supporting discontinuing current grain uses. I will put a copy of their letter signed by the president of the Consumer Foods Group, Jack Stafford, in the record.

[The information referred to follows:]

The Pillsbury Company
Pillsbury Center
Minneapolis, Minnesota 55402

John M. Stafford
President
612/330-8188

Consumer
Foods Group

January 16, 1984

The Honorable William Ruckelshaus, Secretary
Environmental Protection Agency
401 M Street S.W.--Attn: A100
Washington, DC 20460

Dear Mr. Ruckelshaus:

The EDB issue is complicated. However, we believe it is important for the Federal Government to take a position on this issue as soon as possible.

At Pillsbury, we wanted you to know that we are supportive of your efforts and will do whatever we can to help resolve this issue.

After careful consideration of available data, we have developed the attached position. We do not intend to make a public announcement of this position. However, it will be the basis of our response to any inquiry by government and industry representatives, or by our customers.

Please let us know if we can be of assistance.

Sincerely,

JMS:jkt
Attachment

* PILLSBURY POSITION ON EDB - JANUARY 16, 1984

The Pillsbury Company supports the leadership role taken by the U. S. Environmental Protection Agency regarding the use of the pesticide Ethylene Dibromide (EDB).

Pillsbury's analytical data indicates that cooking grain based food products substantially removes any residual EDB which might be present. Company officials said they are confident that all Pillsbury food products are safe.

Pillsbury stated that it would co-operate fully with the EPA in an effort to establish rational guidelines for EDB residues in food. Working through the Grocery Manufacturers Association, Pillsbury will provide the EPA with the scientific data it has collected on EDB. The material will include studies from Pillsbury's laboratories as well as those performed for the company by independent labs.

Pillsbury voluntarily stopped using EDB in September 1983 and supports discontinuing the current use of EDB as a grain fumigant.

* For use upon inquiry by government and industry representatives and Pillsbury customers.

Senator **Durenberger**. Would you as an association support an emergency suspension order?

Mr. **Gardner**. Let me make a couple of points in response to that. Again, EPA has already ordered the end of all further uses of EDB as a grain and spot fumigant, and that cancellation order has been appealed by nine formulators. So as a practical matter, that could delay implementation.

But the important point is that the usage of EDB or its days, in very simple language, are already numbered. Many millers, like the company you mentioned, have informed us that they have stopped using it. So that is the basis for our estimating the risk.

The other point I would make is that the food processors do not use EDB. Whatever residues are found in food are there because the raw grain was treated.

Senator **Durenberger**. One of the questions we were discussing here earlier was the issue of how much contamination might be out there. There seems to be some disagreement among witnesses about the amount of contamination, 2 percent, 5 percent, whatever. Someone quoted your industry as saying it was 40 percent.

I am getting the impression, or at least all of this could leave the impression on somebody out there that we really don't know what the level of exposure is. It is only because Florida and Texas and various States, first alerted to the ground water problem and now to some of these other problems, are starting to generate information and new data. So my question of you then is how can you be so positive that there is or will be no risk when we haven't agreed on the information that we need to make that kind of assessment?

Mr. **Gardner**. The evidence that we have for that lies in the data which have been supplied to us by our member companies. They have taken samples of grain throughout the United States, and those measurements are the ones that, in addition to discussions with other people, provide the basis for our estimate of 40 percent of the grain supply having been treated with EDB.

Beyond the treatment matter is the fact that whether you start with treated or untreated grains, those grains eventually become intermingled in the process of moving from the farm to the mill. So that is a fact. We then have to deal with what is the level of EDB that may exist. Again, the data supplied by our companies show us what levels we may expect, and it is an extensive sample. We now have, or will have when we finish compiling it, several hundred data points that deal specifically with raw grain.

The other important point to make is that given the levels of EDB in grain that we have measured, when that grain is converted into consumable product, we are fairly confident based on the data we have that the level of EDB remaining would not present a risk. It is that information, consumable EDB level, that is the basis for our risk assessment, not what is in the grain to start with, as it moves from the farm to the mill.

Senator **Durenberger**. As I talk to the millers in my State, I really do get the impression that even making assessments about contamination is very difficult because you have such things as the spikes that occur, the first bag that comes off after you have sprayed the roller in the mill with EDB or something like that is going to be very high. The next one will be less high, and so forth.

I take it it would be accurate to say that it is somewhat difficult to do other than arrive at some general conclusions about contamination levels; is that right? There isn't in place a process in which every bag is measured either going out of the mill or coming into General Mills or whatever.

Mr. **Gardner**. That is right. Grain production in this country is widely distributed and there really isn't in place a statistical reporting system that would collect information of this type so that we could make the statement exactly knowing what the level and distribution of EDB is.

Senator **Durenberger**. Let me ask Dr. Rodricks, your review of EDB residues in grain-based products disagrees with that of EPA. Do you also believe the occupational exposure risks to be exaggerated?

Mr. **Rodricks**. No, I don't think so. I haven't looked, sir, at the occupational risks carefully. The reasons for a difference in risk are fairly easily explained. That is for grain product. I am not sure the same reasons would apply to other sources of exposure.

There are three reasons for the difference between our assessment here and that provided by EPA in its last position document for grain products. There are two major reasons and one minor reason. The major reason concerns assumptions about what levels of EDB residues can be found in products as they are consumed. EPA based its assumption about that on very, very limited data. I have looked and reviewed the data supplied by the GMA over the past several weeks and based my assessment on the GMA data, what can be found in products as they are consumed.

The other major reason for the difference is that EPA, and I think properly so, in its position document looked at risks for a full lifetime of exposure. It assumed that people might, if material were not canceled, or its use were not canceled, that people might be exposed for a full lifetime. I, as Mr. Gardner already said, examined the question of risk assuming a limited exposure of 3 additional years. Those are the two major reasons for differences in risk.

The other reason really has to do with some technical problems with the risk model. But that difference is really quite minor.

Senator **Durenberger**. Dr. Nelson, I want to yield to my colleague here fairly quickly, but the levels of EDB found in citrus have been much higher than those found in grain and flour. Is it your opinion that we should be more concerned about exposure through citrus than through grain products?

Mr. **Nelson**. I think it comes down to the extent we can be reliable about this total exposure. We are really concerned with not what is found in the food or grain or flour but what the actual human exposure is. And for the relatively crude predictive purposes that quantitative risk assessment can give us, and I think we ought to recognize it is crude, we can really not make allowance for intermittent possible exposures and so on to any reliable extent. So what one is really concerned about in the last analysis is simply what is the annual rate of intake of the combined source. So one is concerned, of course, with the concentration in one item, but one is also concerned with the actual intake.

Senator **Durenberger**. In your opening statement, your advice to us was to make certain presumptions on the basis of the animal studies on carcinogenicity about humans. I have a quotation here that appeared in the New York Times I think it was back in December of someone involved in this whole process. The quotation goes as follows: We believe that at the levels we are speaking of the food was safe. People have been eating foods with EDB in them for 40 years and nobody has dropped dead.

How would you react to that?

Mr. NELSON. I would doubt very much if we can reliably determine if people are dropping dead from cancer from EDB in food; many people are dying from cancer from many causes. Now to link specific cases explicitly to EDB would be basically an impossible task so far as consumers are concerned: There are many sources of cancer, obviously. Something like 30 percent of all deaths now occur from cancer. The causes are multiple.

I might say, incidentally, and this may help put some perspective on this, that it has been estimated and repeatedly estimated that dietary sources and certainly a lot of cultural factors and so on account for perhaps 30 percent of all cancer.

Now many of these dietary sources, I think unquestionably most of those sources, are age old, millenia old. So what we are talking about here is an addition from a new possible source. We have to say possible potential sources; impacts would be very difficult to discern in the consumer population. It is conceivable it could be discerned in an occupational study involving a sufficient number of persons, sufficient followup period, and so on. It would be futile to look for a study of consumers in respect to cancer from this sort of exposure.

Senator DURENBERGER. Is it a correct summary of your testimony or of your views that EDB is a potent carcinogen and that its use ought to be suspended by EPA as soon as possible?

Mr. NELSON. I guess my reaction to this is it is a potent carcinogen, in repeated tests, in species that are not all that far from man. We must make the presumption that it is potentially carcinogenic for man. Avoidable exposures should be avoided. In fact, I don't even think I hear any objections from the witnesses from GMA, that these can be characterized as avoidable exposures.

Senator DURENBERGER. Senator Baucus?

Senator BAUCUS. Mr. Gardner, I don't fully understand what explains the difference between GMA's figures, as I understand them, which I hear is 1.67 parts per billion, roughly, in processed grain, compared with EPA's figures, which I hear is 31. Sometimes people say EPA is as low as 5. Their staff's testimony I understand to be is not 31, it is 5. I am just curious.

Nevertheless, whatever it is, what explains the difference fundamentally between your figures and EPA's?

Maybe we can help that discussion a little bit by saying as I understand it, you are saying your figure assumed that EDB is banned over a 3-year period. It takes 3 years to work itself through.

Mr. GARDNER. Senator, maybe I can start by backing up just a couple steps and try to lay this out and ask my colleague, Dr. Rodricks, to jump in and save me if I misspeak on this.

The EPA's original consumption exposure was 31 parts per billion. That was the basis for their risk assessment that was published in their October Federal Register notice. That figure of 31 parts per billion was obtained from some limited samples in the laboratory of product that was baked and prepared in the laboratory. They had a small number of samples, perhaps 20 samples at the most, and of a partiuclar type of product, something that I guess we would describe roughly resembling a biscuit. That is the 31 parts per billion figure.

I think that that figure should be compared with the 1.67 parts per billion figure in our risk analysis, which we estimate to be the current dietary exposure, taking into account the different kinds of products that people eat and using the data we have and assigning an EDB level to each of those and weighting the dietary consumption, the 1.67 parts per billion, as the current dietary exposure. The last number, 0.033, is derived from the 1.67 and represents an average dietary exposure that consumers would be exposed to over our estimated 3-year phase-out period.

Senator BAUCUS. At the end of or beginning now?

Mr. GARDNER. The average during that 3-year period. I hope that explains it.

Senator BAUCUS. Now you say EPA used a small sample, 20 samples; is that correct?

Mr. GARDNER. Roughly. My recollection is 20.

Senator BAUCUS. You say something like the size of a biscuit. Does that mean that the total of 20 samples would amount to the volume of a biscuit?

Mr. GARDNER. There were 20 individual biscuits, as I recall the data.

Senator BAUCUS. So they went out and took 20 different biscuits?

Mr. GARDNER. They baked 20 biscuits.

Senator BAUCUS. They baked 20 biscuits?

Mr. GARDNER. Yes, sir.

Senator BAUCUS. I see.

Mr. GARDNER. They took some flour, spiked it with EDB. That is, they added EDB to the flour.

Senator BAUCUS. I see Dr. Rodricks shaking his head.

Mr. GARDNER. That is why I asked him to jump in.

Mr. RODRICKS. EPA had no data on what EDB residues were present in products as they are consumed when they put together the documents supporting this action.

The document published in 1980, which I think you referred to earlier today, PD-23, contains an estimate based on an analysis of the likely residue levels in consumable products, not based on any data of residues in those products, but based on knowledge of how EDB was used and how products were processed.

After that was published, in 1980, EPA scientists conducted a study taking grain already fumigated, containing a wide range of EDB levels, and measured those levels in the flour, and then prepared these 20 biscuits in the laboratory and found an average level in the 30 parts per billion range.

EPA then assumed that that level might apply to all grain products as they are consumed.

Senator BAUCUS. So they took flour they knew was fumigated?

Mr. RODRICKS. Yes.

Senator BAUCUS. Taking flour that it knew was fumigated, although different flour fumigated at different levels, or different grain, resulting in different levels in different flour, it took, nevertheless, flour that it knew came from grain that was fumigated?

Mr. **Rodricks**. That is correct.

Senator **Baucus**. Now GMA's sample, on the other hand, just took an average diet of an average American; is that correct?

Mr. **Gardner**. No, sir. Let me tell you exactly what we did. We took flour that had been prepared in the ordinary course of business and examined that flour for EDB residue. There was no assurance that that flour had been treated with EDB during the milling process. We were dealing with random samples from the production of flour. There were some other tests which were done in which EDB was deliberately added, and that was a relatively small number of samples. But for the most part, the flour that we dealt with, it could have been flour from wheat or from corn, was taken from the regular process. That flour was then analyzed to determine how much EDB it contained. Some of those EDB-containing and non-EDB-containing flour samples were then prepared into different kinds of products—bread, cake, cookies—in the laboratory, but using commercial cooking processes to produce the bread, cake and cookies. Those in turn were then analyzed for EDB content.

So the purpose of that work was to determine what happened to the EDB level as it moved from the flour stage into the product that is ready to be eaten.

Senator **Baucus**. You say EPA had only 20 samples, roughly 20 biscuits. How widespread were your samples?

Mr. **Gardner**. I don't have the number offhand, but there were several dozen at least.

Senator **Baucus**. Several dozen?

Mr. **Gardner**. Yes.

Mr. **Rodricks**. More than that. I prepared my risk estimate on the basis of several hundred. I think it was 500 or 600 samples of consumer products, a variety of different consumer products; cake, pasta, for example.

Senator **Baucus**. So you took 500 or 600 samples selected randomly?

Mr. **Rodricks**. Yes; around the country. I am not sure of that number.

I am sorry; I was thinking of a different list. It is about 200.

Senator **Baucus**. About 200?

Mr. **Rodricks**. Yes.

Senator **Baucus**. I don't want to get too technical here. What was the size of the sample? You say average sample. The size of a glass here, or is the average sample a micron? What are we looking at here?

Mr. **Gardner**. A sample is a loaf of bread or a cake or a doughnut.

Senator **Baucus**. So it would be a loaf or a cake?

Mr. **Gardner**. That is right. And a piece of that bread or cake, or whatever, was then analyzed.

Senator **Baucus**. Does EPA dispute, so far as you know, your characterization of how they took their samples? Do they agree with your characterization as to how they took their samples, or do you know?

Mr. **Gardner**. I don't know.

Senator **Baucus**. That is not in dispute then?

Mr. **Gardner**. That has not been a problem.

Senator **Baucus**. So far as you know.

Mr. **Gardner**. No, not in dispute.

Senator **Baucus**. I should have asked this question of EPA. Would the same apply as to EPA's characterization as to how you took your samples? Do they agree so far as you know and they understand and agree with the way you took your samples?

Mr. **Gardner**. Well, I hope they understand and agree.

Senator **Baucus**. So far as you know, that is not in dispute?

Mr. **Gardner**. That is not in dispute as far as I know.

I might offer at this point my understanding of where they are is that they have moved off of or moved away from the 31 parts per billion estimate and now have some other number in mind. I don't know what that other number might be. But it is different from the 31 parts per billion.

Senator **Baucus**. Dr. Nelson, just a question for you. It is a tough question to answer. But I would just like your answer to it anyway. That is the degree to which medicine today really knows what causes cancer. I read an article where to some degree some scientists say that it is DNA compositions and it is chromosomes that have a lot to do with whether a person is going to get cancer, or certain kinds of cancer, as compared to whether that person is not.

So the question is the degree to which certain agents then interact with chromosomes and cells and DNA combinations and so forth, do we really know? How much have we progressed on the one hand in knowing what causes cancer and on the other hand how much farther do we have to go to start nailing some of this down?

Mr. **Nelson**. I feel very confident that over the last really quite recent years, 10 to 15 years, we have come to understand a great deal about how certain kinds of chemicals produce cancer. I think the thread is pretty continuous, pretty good, that the steps involve an interaction with DNA, an alteration, which does not kill a cell but alters its genetic propensity. This then alters the growth pattern of the progeny of the cells, now talking especially about body cells, not inherited cells, and these cells have altered growth patterns. That altered growth pattern may take the form of an irreversible, unstoppable cancer.

Now that applies to agents, to use the jargon, electrophilic aqents. They are agents which have the property of reacting very rapidly with big molecules, not only DNA but protein molecules and so on.

Senator **Baucus**. I guess my question is——

Mr. **Nelson** [continuing]. A little less complicated than that.

Senator **Baucus**. We don't have time to go into that.

Mr. **Nelson**. I have just one more addendum. We are talking about a specific class of organic chemicals. This is a very dubious relevance to cancers that involve hormone sites, breast cancer and metals. But I think we feel reasonably comfortable. Details are missing. But there is I think confidence that there is a sequence of events here which lead us to be confident that these tests are useful predictors of carcinogenicity.

Senator Baucus. According to the present state of the art, to what degree are some people more exposed to getting, certain kinds of cancer due to certain chromosome patterns and so forth? How much do we know about that?

Mr. Nelson. Very little.

Senator Baucus. What potential is there in that area?

Mr. Nelson. Let me give an example. Only a fraction of persons smoking three packs of cigarettes a day get lung cancer, not all persons. The reason for the difference, for the susceptibility of some and resistance of others, is almost certainly genetic. They are built into the host, although prior disease might influence it. You may be strongly resistant where I am weak and frail to certain kinds of outside assaults.

Senator Baucus. Thank you very much.

Senator Durenberger. Senator Abdnor?

Senator Abdnor. I would just like to ask a question along that line. What is the least particle of measurement that you can pick up of EDB in grain, for instance? How low can it be and still be measured? Would you tell me that, Dr. Rodricks?

Mr. Rodricks. The survey conducted by GMA was conducted with analytical methods capable of measuring one part per billion, one part of EDB per billion parts of grain.

I am not expert on the analytical chemistry, but I understand that to be the limit of detection of EDB residues in grain products.

Senator Abdnor. Is it really possible we could have grain coming in treated by this and they couldn't even measure it?

Mr. Rodricks. I am sorry?

Senator Abdnor. There are undoubtedly considerable bushels and tons of grain coming into the mill that have been treated with EDB that won't be picked up as having any particles at all.

Mr. Gardner. One part per billion is a very, very small amount to measure. It may be possible that there is some amount less than that in grain, as you suggested, Senator Abdnor.

Senator Abdnor. If it is down that low, is it a serious concern? I don't want to belittle it. I just want to find out how serious this thing is.

Mr. Gardner. There is a two-part answer to the question. One is that I am sure we are concerned when there are substances present in foods we don't want to be there. On the other hand, based on the data and understanding we have, those levels that are there do not pose a significant risk to people.

Senator Abdnor. I am not questioning the fact we don't want it there. But it is there and we have to be realistic and practical and prudent on this thing. We can't just jump in without any figures and facts and suddenly make a lot of charges. I think I read somewhere that Florida uses that one particle per billion as a standard. Is that right?

Mr. Gardner. Yes, sir.

Senator Abdnor. Isn't that kind of ridiculous? Do they base it on anything other than a figure out of the sky? This has to have very serious consequences, I would think, to the producers in that State. If they really have some concrete evidence, that is one thing, but just to pull a figure out, I just wonder how sound their figures are and their reasoning.

Mr. Gardner. Florida's enforcement level of one part per billion was adopted simply because that was the lowest level that they were capable of measuring.

Senator Abdnor. Why don't they just abolish it then? That would be the same thing, wouldn't it?

Senator Durenberger. We have a witness here from Florida.

Senator Abdnor. I am glad to hear that. I hope I am still here. That is all.

Senator Durenberger. Max, anything further?

Mr. Gardner. Mr. Chairman, if I may, Senator Abdnor touched on an important point, and Dr. Nelson raised it earlier when he remarked about the advisability of exposure to EDB. I think we would agree that exposure to EDB is avoidable in the future. It is not avoidable today, given our understanding, based on the measurements we have of the grain supply and the product prepared from grain. Now although the exposure is, in our estimate that is derived from the data, low and insignificant, it is not avoidable at least for the next 3 or so years.

Senator Durenberger. And to the extent it is in the underground water supply, that is a lot more than 3 years.

Mr. Gardner. That is another issue. That is true, Senator.

Senator Durenberger. The flip side of it, though, is, say, on the occupational side, that one might be terminated much earlier than on the consumption side. Am I making your point for you?

Mr. Gardner. Yes, sir.

Senator Durenberger. The last point I want to clarify here is about where EPA got their information on the risk assessment, where you got yours, and so forth, to make sure we understand this, because Dr. Nelson was giving us advice and making some comments on EPA risk assessments.

As I understand it, EPA's assessment was based on total dietary exposure, whereas GMA's was based on exposure to products of companies who are members of GMA, who I am assuming are a subset of all food producers, so not necessarily quite the same base. Just try to clarify that for us.

Mr. Gardner. I will try, sir.

The EPA's estimates had to do with exposure from grain products. Their estimate was based on those samples we described earlier as the level of exposure. Our estimation was done in a similar way, but using a different data base and using a data base that was required in terms of the kinds of grain and the kinds of product that people consume and adjusting the exposure based on our understanding of what people do eat. But the bottom line is that the estimating techniques were similar.

Senator Durenberger. Does anybody else have any questions?

Thank you, gentlemen, very much. I appreciate your being here. Dr. Nelson, you particularly, on short notice. Thank you for coming down.

[Mr. Gardner supplied the following response to additional questions from Senator Durenberger:]

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United States Senate
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, D.C. 20510

February 10, 1984

Mr. Sherwin Gardner
Vice President
Science and Technology
Grocery Manufacturer's Asso. of America
1010 Wisconsin Ave., N.W.
Washington, D. C.

Dear Mr. Gardner:

As a follow-up to the hearing on ethylene dibromide on January 27, I would appreciate your providing a written response for the record to the following question:

> You stated in response to a question that "... food processors do not use EDB. Whatever residues are found in food are there because the raw grain was treated." That statement contradicts other information in the record. Are you overlooking EDB use as a spot fumigant on grain milling machinery, or do you mean to say that spot fumigation does not leave EDB residues in flour subsequently milled in the fumigated machinery? Do you have any actual data on this latter point?

Please provide your responses within two weeks. For editorial purposes, please record each question with your response immediately following. Please deliver the original copy of your response to the Committee on Environment and Public Works (Attn: Ron Outen) for inclusion in the hearing record, and deliver copies to Senator Baucus and me.

Thank you for your efforts in providing this additional information.

Sincerely,

Dave Durenberger
Chairman
Subcommittee on Toxic Substances
and Environmental Oversight

GMA
SHERWIN GARDNER
Vice President, Science and Technology

February 28, 1984

The Honorable
Dave Durenberger
U.S. Senate
Washington, D.C. 20510

Dear Senator Durenberger:

This is in response to your letter of February 10, 1984 in which you raised a question about the use of EDB by food processors.

In describing the users of EDB it is necessary to distinguish between the manufacturers of packaged consumer foods and those producing flour or meal as ingredients for use in those foods. Clearly, some producers of flour are also manufacturers of packaged foods. Most packaged food manufacturers, however, are not millers; most GMA members are not millers. Millers were users of EDB for spot fumigation; such usage does contribute to EDB residues in food.

Thank you for the opportunity to provide this information.

Sincerely,

Sherwin Gardner

Sherwin Gardner

SG:et

cc: Ron Outen
Senator Baucus

Grocery Manufacturers of America, Inc., 1010 Wisconsin Avenue, N.W., Washington, D.C. 20007•(202) 337-9400 • TWX: 710-8229364

Senator **Durenberger**. I am going to call two people: Senator Proxmire, who is here for his 11 0'clock appointment, and we appreciate your being here; and Dr. Gilles, why don't you come up at the same time. We keep putting you off here, and you have been very thoughtful and very kind. I don't want you to be able to escape either our attention or our efforts this morning.

Bill, thank you very much. I know of your interest in this area for a long period of time. We appreciate your taking the time to be here. Your full statement will be made part of the record. You may do whatever with it.

STATEMENT OF HON. WILLIAM PROXMIRE, U.S. SENATOR FROM THE STATE OF WISCONSIN

Senator **Proxmire**. Thank you very much, Mr. Chairman. I will be brief. I have a short statement which I will read.

I apologize for not having the copies for the committee, but as you know, this is kind of a last-minute operation and the copies have been duplicated. They should be made available to you within the next 3 or 4 minutes.

Thank you for giving me the opportunity to appear before you today on the subject of ethylene dibromide, better known as EDB.

EDB has been used as a pesticide for over 30 years. Initial cancer testing in 1974 and 1975 verified that it is one of the strongest carcinogens ever investigated by EPA. Even worse, in addition to cancer, EDB also causes inheritable genetic mutations and reproductive problems, including sterility. Yet, although the Agency has had the benefit of 10 years of data, it has done little to protect the public from this threat.

After a slow start, EPA's actions against EDB ground almost to a complete halt in the last 3 years.

Despite the desire of some in the Carter administration to issue a cancellation of most uses of the pesticide in 1980, EPA took no further action until September of 1983, and then only in response to widespread reports of EDB ground water contamination in several States. Even that response was inadequate because EPA exempted many uses of the product for several more years.

Despite the known hazards presented by EDB, EPA set no standards for EDB contaminated food; instead, the Agency relied on erroneous data from the 1950's which greatly underestimated human exposure levels. And EPA trusted outmoded scientific tests which could not detect EDB molecules, giving the Agency a false sense of security.

But EPA no longer ignores the evidence. According to the EDB position document issued in September of 1983, the Agency admits that EDB is potentially capable of producing adverse health effects in humans and that "no remedial changes can be made in the registration of EDB for most uses to avoid unreasonable adverse effects on human health."

EDB is not an isolated case of Agency inactivity in the face of known danger. Delay, secrecy, and bad science are built right into the Federal Insecticide, Fungicide and Rodenticide Act, making protection of the public difficult at best.

Data are missing on many of the most commonly used pesticides. Most of the chemicals which date back before the modern pesticide law was enacted in 1972 have never been subjected to real scientific scrutiny.

According to a recent study by the House Agriculture Committee which used EPA's own records: Between 79 and 84 percent of the products on the market have not been adequately tested for their capacity to cause cancer; between 90 and 93 percent of the same products have not been adequately tested for their ability to cause genetic damage; between 60 and 70 percent have not been fully tested for their ability to cause birth defects; between 30 and 46 percent have not been fully tested for reproductive effects. And even those pesticides recently tested may give cause for concern.

Nearly 15 percent of all the pesticide chemicals approved by EPA for use on the U.S. market have been registered with faulty or fraudulent health and safety data produced by the Industrial Bio-test Laboratories, Inc. According to the EPA audits of other laboratories across the country, the public has ample reason to worry about test quality.

To make matters worse, EPA has issued wholesale exemptions from its safety rules. Between 1978 and 1982, the issuance of emergency exemptions under the "specific," "crisis," and "other" categories rose from 149 to 673, a 352 percent increase. By the end of fiscal 1982, the EPA had granted a total of 8,650 special local need registrations. This is really administration by exemption.

Mr. Chairman, administrative remedies alone can't correct FIFRA's deficiencies. Only new legislation can insure that EPA will fill the gaps in basic data uncovered by the House Report. In 1972 we gave the Agency 3 years to reregister all pesticides registered prior to 1972 in order to subject them to the scrutiny of modern scientific ~~testing~~.

But it is now 1984, and reregistration is moving at a snail's pace.

To correct these deficiencies, I have introduced new legislation, S. 1774, which reforms FIFRA. Without it, American consumers will continue to be subjected to a catastrophe of the month syndrome.

S. 1774 mandates specific timetables for reregistering pesticides based on a list giving priority to those pesticides used in the highest volume on food or feed crops or those expected to cause mutations and cancers. The EPA Administrator is also required under S. 1774 to publish a list of all gaps in the data for pesticides being reregistered. Gaps must be filled within 3 years.

These reforms and others contained in the bill will insure that only pesticides proved safe will be used on food or spread throughout the environment.

S. 1774 also gives special attention to ground water pollution by pesticides. It directs the Administrator to consider potential ground water pollution in deciding whether to classify pesticides for restricted use, to be applied only by trained applicators.

These are just a few of the provisions contained in S. 1774. Each has bearing on the case of EDB. If all the data on EDB were adequately developed, it is unlikely that EPA would have continued to allow its widespread use.

I might just say that the bill is pending in the Agriculture Committee. Hearings have finished in the House. They have had a 1-day markup, but they haven't completed their markup, and they are expected to complete it shortly.

Thank you very much.

Senator **Durenberger**. Thank you very much, Senator Proxmire. Max, do you have any questions?

Senator **Baucus**. No; thank you.

Senator **Durenberger**. Senator Abdnor, any questions?

Senator **Abdnor**. No.

Senator **Durenberger**. Thank you very much for your commitment and statement and for coming today. We appreciate it a good deal.

Senator **Proxmire**. Thank you.

Senator **Durenberger**. Mr. Gilles, thank you very much for your patience. We welcome your being here today. Your written statement will be made part of the record. You may proceed to summarize it.

STATEMENT OF KENNETH GILLES, ADMINISTRATOR, FEDERAL GRAIN INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY BILL HELMS AND DICK PARRY, AGRICULTURAL RESEARCH SERVICE

Mr. **Gilles**. Thank you very much, Mr. Chairman. I have asked Mr. Bill Helms, from APHIS, and Mr. Dick Perry, from the Agricultural Research Service, to join me at the table, although I will endeavor to be the primary point of the presentation.

We do welcome this opportunity to discuss the pesticide, ethylene dibromide. We want to point out some general facts about EDB and then address its postharvest use as a grain fumigant perhaps in more detail.

We will endeavor not to go over the same ground previous speakers have testified on. But for point of reference, EDB has been registered for use as a pesticide since 1948. It is a halogenated hydrocarbon. It is a volatile liquid and used primarily as an additive in leaded gasoline. The annual production has been estimated to be about 300 million pounds, more than 90 percent of which is used in gasoline. The National Cancer Institute has cited this source, inhalation of vapor, as a primary point of concern.

In 1983, approximately 5 to 7 percent was used for agricultural purposes. The principal use was as a soil fumigant, to rid the soil of nematodes which affect peanuts, soybeans, vegetables, and pineapples primarily.

EDB has also been used as an onfarm fumigant for grain elevators and as a spot fumigant for insects in flour mills.

The current information indicates that the uses have decreased significantly. The National Grain and Feed Association, the North American Export Grain Association, and the Millers National Federation have indicated to us that their member organizations have voluntarily stopped using EDB.

Its use as a quaratine treatment, however, for fruits and vegetables deserves some special concern from the Department's standpoint. EDB is used as a postharvest control for the Mediterranean, the Mexican, Oriental, melon, and Caribbean fruit flies. There is no alternate effective treatment that will provide American agriculture the protection necessary to prevent the spread of all these destructive pests in all commodities and markets.

Most of the citrus fruits from Texas and Mexico must be fumigated with EDB prior to their being shipped to California, Arizona, Texas, and Japan. California accepts Florida fruit fumigated with methyl bromide, but the other States and Japan require EDB fumigation. Thus, the loss of EDB would seriously affect the commerce of the domestic growers in the United States as well as many foreign countries.

USDA believes that alternatives are available to EDB for soil fumigation, for grain treatment, and for spot mill fumigation. The alternatives may not be as effective or as economical as EDB itself, but they are available.

USDA has for a number of years been cooperating with industry and the States to test alternative technologies to control fruit flies in the impacted commodities. This has resulted in Japan and California approving a cold treatment procedure on grapefruits from Florida. However, other citrus and tropical fruits will require separate technologies for each pest and commodity. The use of sterile flies and detection activities are also being explored as well as evaluation of other chemical fumigants, various temperature exposures and mixtures of gases.

Speaking more specifically of the grain issue, during fiscal year 1983, approximately 393 million metric tons of grain was produced in the United States. During the same period, 176 million tons were voluntarily inspected under the U.S. Grain Standards Act in the domestic market. In addition, some 114 million tons were mandatorily inspected for export use.

Now, under the U.S. Standards for Grain, the presence of live insects injurious to stored grain causes the grain to be graded weevily. This lowers the economic value of the grain. In addition, insects in grain constitute a potential public health hazard as well as an economic problem. To correct this, fumigants have been used to kill insects so the grain will not be graded as weevily.

There has been considerable publicity concerning the amount of U.S. grain in storage that contains EDB. A team of officials from the USDA, EPA and the States determined, through an assessment report, that only 2 to 5 percent of the grain in storage had been fumigated with formulations containing EDB. Now we must recognize that grain is commingled during transportation and marketing. Attached to this statement is a diagram which illustrates this commingling process. This blending of EDB treated grain with nontreated grain could increase the percentage of the total grain supply which contains detectible traces of EDB.

Considerable speculation has been given to the level of EDB residues in fumigated grain. Some 30 samples were collected from our Federal Grain Inspection Service and tested. These samples originated from several different locations throughout the United States.

Of the 30 samples, EDB was not detected in 21, and the 9 remaining samples averaged less than six parts per billion of EDB. The maximum found in any one sample of that particular group was 22 parts per billion. A more complete description of this information is attached as a supplement to the statement.

We are currently working with EPA in developing a larger data base in which some 400 samples, 200 of corn and 200 of wheat, taken from 15 field offices, and in proportion to grain that has been exported through those offices, are tested. Each sample taken by an automatic sampler represents some 60,000 bushels of grain. These samples are now being analyzed and the results will be given to EPA by January 31.

In addition, portions of those samples were given to EPA's laboratory at Beltsville so that they can conduct an independent check on the qualitative procedure. These samples, however, are not statistically representative of the total grain in storage. I think this is an important issue.

Our sources indicate very little EDB presently is being used commercially in liquid grain fumigants. Most of the liquid fumigants contain from 1 to 5 percent EDB and are distributed in 1 and 5 gallon containers, which suggests that small quantities are applied primarily to farm-stored grain. The grain industry contends that it is not using EDB as a fumigant.

Parenthetically, I would indicate I have been assured by many that they have not used it for many years.

To eliminate public concern about EDB in the Nation's food supply, and to avoid disruption of the food distribution system, and to avoid economic hardship for those who have grain previously fumigated with liquid fumigants which may contain traces of EDB, or who currently may not have a satisfactory alternative for onfarm fumigation, it may be appropriate for EPA to establish reasonable, interim guidelines based on data derived from the USDA, EPA, and other sources such as the grain and milling industries and the Grocery Manufacturers of America.

To further assist the EPA, a protocol has been developed between ARS and EPA to determine the fate of EDB during corn processing. This work is expected to be completed by September.

Mr. Chairman, this completes our formal statement. We would be prepared to respond, to the best of our ability, to any questions you may care to ask.

Senator DURENBERGER. First, sort of a basic question for the record, and I think I know the answer to this, but you indicated that some fumigants are going to be used at the point of farm storage so they are being applied at that stage. Sometimes it is applied when the grain is delivered to an elevator. Then it can be applied somewhere after it has been sold out of the elevator for delivery somewhere. And I suppose that is perhaps at some point a transshipment or maybe even where it is being delivered for processing; for example, in the mill.

Am I basically accurate on that, or would you embellish on that?

Mr. GILLES. Senator, I think you have very succinctly summarized it. Much of the grain on the farm is not routinely fumigated. Generally the farmer is in need of cash flow, so postharvest marketing action is generally started at the farm level or to move grain on to the country elevator.

However, for those instances where grain is stored on the farm, the fumigants usually are applied if the grain is held for an extended period of time, usually a year or more.

It is for these reasons we believe that the amount of EDB that is actually applied is quite low. Certainly the pounds of EDB that have been used would substantiate these low numbers.

Senator **Durenberger**. Is it true to say that you, the Federal Grain Inspection service, and the farmer have basically the same interest? You don't want bugs in the grain because it is your job, along with State inspection services, to deal with the quality of grain, and a large part of that is whether or not it has been in some way contaminated not by chemicals. I take it that is not your business. Is it?

Mr. **Gilles**. No; a chemical would be an additive.

Senator **Durenberger**. What is your business? What are you looking for then in the product?

Mr. **Gilles**. The Federal Grain Inspection Service is constituted to inspect grain primarily from the standpoint of the biological and physical condition of the grain at the time of inspection. We can on request, of course, look for other additives.

For example, if there is concern that a toxin is present, we do have chemical tests to evaluate that. Because there has not been a great amount of concern about EDB in the past, we do not routinely test for EDB.

Another problem is that the time lag in testing for EDB is very substantial. Generally the tests that we use can be conducted in a short period of time, 15 minutes to an hour at the most, whereas, the testing procedure; for EDB, depending on which variation you use, is going to require 1 to 4 days before the analysis is completed. In that 4-day period there would be substantial demerrage costs for rail cars or for ships.

Senator **Durenberger**. I want to ask that question, even though I may know the answer myself, because it is quite possible that based on your testimony, that your working with EPA and making some recommendations to them that people are going to get the impression that somehow the inspection service is expert on all of the problems here. On the other hand, there are going to be a lot of people that are going to charge the Department of Agriculture with spending more time and effort as an apologist for the chemical EDB than it has looking for some kind of a safe and effective alternative.

I take it you have been head of the inspection service a lot longer than Mr. Moore has been head of his division of EPA. I wonder if you can give us any kind of estimate on the resources, dollars, people, that the Department of Agriculture has committed to finding alternatives to EDB.

Mr. **Gilles**. In spite of the fact that I have been in my place perhaps a little longer than Mr. Moore, I don't know that I have hard numbers for you. May I ask my colleague, Dr. Parry of ARS, do you have any idea?

Dr. **Parry**. I will attempt to make an estimate.

The Agricultural Research Service of the Department of Agriculture is charged with developing alternatives to assure a safe and wholesome food supply. We have devoted resources for review of ethylene dibromide ever since the initial announcement of the Environmental Protection Agency.

Senator DURENBERGER. Which is when, ever since the initial announcement.

Mr. PARRY. The initial announcement by the National Cancer Institute was in 1973-74.

Senator DURENBERGER. 1973?

Mr. PARRY. Yes. Most of these activities have been devoted to the development of alternatives for quarantine treatment of fruits and vegetables. The ARS level of expenditures is $1.589 million in fiscal year 1984 for EDB alternative technologies. There has been considerable activity as well in many other basic research activities on protecting stored products, particularly grain, and various other commodities as well. The total ARS fiscal year 1984 budget for new quarantine treatments is $4.7 million.

Senator DURENBERGER. Thank you for the information in view of what I am going to read. I don't know the author of the publication, but I inserted in the record earlier on the article from the most recent issue of Science magazine in which the author says as follows: "Despite EPA's desire to regulate the pesticide since 1977," as you indicated, "efforts at USDA to help farmers and citrus growers have been meager." You said $1.589 million. "According to the recent study on EDB by the GAO"—they must have characterized it as meager—"the GAO said that studies by USDA have been 'limited to short-term research projects. This crisis-oriented research resulted in the postponement of broader scope, longer-term research." It noted, GAO I guess, "that since 1977, it has twice advised USDA to develop an agency-wide plan for research and development, but to no avail. An EPA official recently put it this way: 'Without an all-out cancellation, the industry wouldn't consider an alternative. Now we are canceling and they are screaming that there are no alternatives' ".

Maybe, Dr. Gilles, you would want to comment on that?

Mr. GILLES. I think that Dr. Parry might be the more appropriate person because he is part of the ARS team.

I, however, would react that indeed the Department is taking a very serious view of this matter. And in terms of alternatives, as I indicated in my statement, there has been work conducted on looking at such alternatives as temperature control, as alternative gases, including storage for grain, perhaps inert gases. This work has been an ongoing affair.

Perhaps looking back progress is not as rapid as we wished it had been, but nevertheless, there has been a commitment I think in post-harvest technology for some period of time, within ARS.

Dr. Parry, would you care to comment?

Senator DURENBERGER. Why don't we turn to your colleague on your left, yes. I am sorry.

Dr. PARRY. USDA is trying to develop several quarantine treatments to replace a single broad spectrum fumigant. There are five fruit flies that are of concern to quarantine officials. Each behaves differently or has different degrees of susceptibility to kill. Each commodity responds differently to quarantine treatments, which are called phytotoxic or fruit damaging effects. So, therefore, you have differences between the various types of citrus, grapefruit being the most sensitive, papaya, mango, and other vegetables.

There are different marketing systems for fruits and vegetables ultiiizing land, air and sea shipments. For example sea shipment for Florida grapefruit to Japan takes about 22 days whereas it takes 3 days for shipments to California. Therefore, it has not been possible to come up with a single alternative to EDB for all cases.

This situation has required that we develop alternatives custom made to each fruit and vegetable. We have tried to avoid putting all our resources into short-term solutions because these short-term solutions may be chemical solutions and they may come back to haunt us. We have tried to develop alternatives that involve temperature manipulation of a product, not only to kill the insect but perhaps even to enhance the fruit quality. We have developed a cold treatment process which is quite adaptable for the Florida to Japan grapefruit market. This involves cold tempering the fruit for seven days and then lowering it to near freezing for a period of 19 days. This is easily adaptable for a sea freight system and many commercial tests are being carried out right now to see if it is a viable alternative to EDB fumigation.

The Japanese have approved, this as a quarantine method to control Caribbean fruit fly. However, we, at this point in time, are still trying to get an evaluation of the product damage that a shipper can expect during the course of an entire season, because the characteristics of a grapefruit change from the early season to the late season. Therefore, alternatives must be evaluated over a period of time to be sure the economics and marketing are viable in actual commercial practice.

This long-term treatment, 26 days in cold, is not adaptable for Florida fruit going to California.

Senator **Durenberger**. I take it none of them are complete substitutes for EDB in either the citrus or the grain market today.

Dr. **Parry**. Well, the Department is preparing a report, as directed by the House, on the alternatives for EDB fumigation of fruits and vegetables, and in what stage of development we are. This is being prepared right now and it will be released on February 15 by the House Committee on Agriculture. (See p. 268.)

Senator **Durenberger**. Will there be anything in there that will tell us what our trading partners are doing? As I said earlier, you have three big grain States represented by three Senators. We spent a lot of time on sanctity of contract and export credit controls and jokes like PIK and a variety of other things, trying to move this product, and we don't want all of those kinds of efforts, which are very costly to this country and the producers, to be defeated, that is the whole point of this series of questions, to be defeated by a lack of public knowledge and understanding of a problem like EDB or the failure on the part of people who ought to know there is a problem since 1977 to help us find alternatives in the system. That is the purpose for this line of questioning.

Now, what do we face when we get to the world market? How about Brazilian grain? I can understand the Canadians. It is as cold up there as it is in Minnesota. They aren't going to see a lot of fumigants used, if any, in stored grain in Minnesota, and you are not going to see it in Canada. That presents a problem for a lot of folks. If we shut down the current fumigant technology in this country, Canadian grain ought to be the first one on the market. How about Brazil or the Argentines or somebody else that doesn't live in a frigid climate?

Mr. **Gilles**. I will endeavor to respond to that. I think you will find that other countries are also confronted with the same problems. Indeed, some of the other countries are using EDB for their postharvest technology. However, as you study the countries of the world, their internal laws may differ from ours. Their ability to use technology differs from ours. But as far as insects are concerned, there are a number of insects that do trouble the grain that moves from Argentina, for example, into world markets. They are plagued with similar kinds of problems. As long as the moisture and the temperature and the food supply is there, insects can preliferate.

May I return to one other component? I believe Dr. Parry correctly addressed the role of the Agricultural Research Service. But there is another component in this system. Each of the several States is funded in part by the Department of Agriculture to support an Agricultural Experiment Station. The purpose of these stations is to address the research needs of those States. The States you represent would have a greater amount of interest in grain than States like perhaps Maine or Connecticut. So there is another component of this whole system that I don't think was adequately addressed in the "Science" article.

Senator **Durenberger**. Senator Abdnor?

Senator **Abdnor**. Maybe my hearing is bad. I didn't quite catch that. Are you suggesting maybe we are better off with these States setting their own level? Did you say that?

Mr. **Gilles**. No; if I left that impression, it was unintended. I merely meant to clarify the point that there are two major research thrusts: The thrust which is centered here in Washington through the Agricultural Research Service and through a companion in the Cooperative State Research Service, which relates to the State experiment station in each States. The purpose of that work is to provide the States with an opportunity to work on agricultural problems unique to that State or the region in which that State is located. We do research work in a companion manner.

Senator **Abdnor**. Let me ask you this: As long as we are on this subject, is it possible that if nothing is done, each State can set their own levels, and we could have one big problem? I mean the producing State might have one level and some other State have a level that they couldn't bring the food in.

Mr. **Gilles**. I presume that is one scenario. I guess the reason we ended the formal statement as we did is that USDA is encouraging EPA to establish reasonable tolerance levels.

Senator **Abdnor**. What is reasonable?

Mr. **Gilles**. That is to facilitate the interstate movement of food products and to protect public health.

Senator **Abdnor**. What is a safe level? What do you see as a safe level?

Mr. **Gilles**. That is a very difficult question to answer, Senator.

Senator **Abdnor**. Sorry to put you on the spot, but if you can't even measure it until you get to one particle and some States are using that, that sounds pretty ridiculous, unless they have more facts than I have heard about to date. What do you think is reasonably safe, in your judgment?

Mr. Gilles. I think that the State of Florida took precipitous action in declaring the action level at one part per billion because that is the minimum detectible limit of a relatively new technical method, only published in 1981. I think that as we look at the grain industry, if EDB were to be banned as far as the grain handling equipment is concerned, there are alternatives available.

Senator Abdnor. That one particle, they could just as well put a complete ban on using it then; is that right?

Mr. Gilles. Yes. To the credit of the grain industry, they have not raised an objection to the banning of EDB.

Senator Abdnor. We could use something else to fumigate the grain. I have to find out what my people in South Dakota are using. But apparently, for citrus fruits, this is the only known way today; isn't it?

Mr. Gilles. The citrus fruits we believe to be a problem, yes.

Senator Abdnor. How much are they finding? How many particles in an orange are they finding, or grapefruit?

Mr. Gilles. I think Dr. Helms of APHIS would be the appropriate person to respond.

Dr. Helms. I don't recall what the actual figures were. EDB in citrus has a curious mode of action. EDB being six times as heavy as air, for an example, it is very difficult to get it to leave fruit. We have done some work in cooperation with EPA and OSHA in 1981 in which we took some fruit from Florida that was fumigated with EDB. We tried to inject in the transportation system some things to reduce the levels; We were primarily concerned with the worker exposure, but also measuring residue.

As an example, when a truck gets to California, you open it, and the amount in the fruit is quite high I don't recall the figures. But for our purposes, let's assume it was in the neighborhood of one to two parts per billion. EDB has the ability to continue to off-gas. As that off-gassing occurs, the residue in the fruit itself gets less and less.

I will be glad to furnish for the record any data we might have on the residue. But it would not be uncommon, I don't think, to find a ten-fold reduction by the time that product got to the marketplace.

Senator Abdnor. One to two particles is maximum. If that was going out of my State, you would hear me scream.

Senator Durenberger. If you would yield for a second, Jim. There is some information from the California Department of Food and Agriculture on this very subject. (See p. 156.)

Using samples drawn from retail grocery stores, the answer to your question would be, just as an example here, in the period January 4 to 12 of this year, testing the pulp of Florida grapefruit—and this was mostly Florida, some Texas and Mexico—but just using the pulp from Florida grapefruit, 250 parts per billion, another batch 350 parts per billion, another 200 parts per billion, another 60, another 380, another 17, another 300. So there appears to be that kind of dimension, at least in California where they are looking at Florida. Mexico pulp, that is oranges from Mexico, 420 parts per billion in the pulp. Here is oranges from Mexico in Downey, Calif., 1,420 parts per billion.

Senator ABDNOR. But the oranges come from Mexico?

Senator DURENBERGER. Mexico, Florida. Texas is pretty good, zero in one case and 16 in the other. But this is in the record.

Senator ABDNOR. Thank you. That is helpful.

The big thing with EDB is what they found in the water; is that right? Is that from an excessive amount being sprayed on the ground, or what?

Mr. GILLES. The contamination in the water supply is believed to originate from the application of EDB on soil to treat for the nematode, which is a worm that attacks the roots of many of the plants, and then by percolation, we presume the fumigant has gone to the water supply.

Senator ABDNOR. Can grain elevators detect EDB? Are they in a position to determine the amount of particles of EDB in grain?

Mr. GILLES. The detection of EDB is a rather complicated process. I know of no grain elevators, for example, in South Dakota, Senator, that would have the capability of analyzing for EDB at the spot. The possible way that EDB detection could be effected would be to sample the grain and then send those samples in a sealed container to some technical laboratory that would have the capability of using gas-liquid chromatography.

Senator ABDNOR. GMA was testifying here that 40 to 50 percent of the grain delivered to food manufacturers contains EDB, but that the foods prepared from these grains contain very low levels of EDB. Would you agree with the numbers in that statement?

Mr. GILLES. I have no reason to either agree or not agree with those numbers, sir, primarily because it is our opinion that the amount treated is very small. I think I heard the gentleman use the word 40 percent treated. If that is what he meant, I would disagree with that point. I would think that 40 percent might contain some traces of EDB only through the fact that grain is commingled. As grain moves from the farm to a country elevator, it moves into an elevator, in which other farmers' grain is also stored, some of which may contain traces of EDB, some of which may not. But as grain moves through the marketing chain, traces of EDB, using the one part per billion analysis approach, might be detected in the grain.

Senator ABDNOR. Mr. Chairman, up in the northern country of Minnesota and Canada it is not a problem. South Dakota isn't exactly warm. Let me tell you, almost every bin of grain has been sprayed up there, I think. At least I got a bill for a heck of a large portion of it, some that I was involved with.

Also I know how sometimes when you bring a truckload of grain into the elevator, some people years ago used to slip in a little seed grain, they treated it, and that could contaminate a large bin and that could happen. But 2, 3 percent of the grain is all that is being affected, I just don't think that is quite accurate. I would have to believe that the fact you can't measure below one particle per billion is more the problem of detecting it than anything else. Do you believe that the current levels of EDB in food represent any health hazard to the American public today?

Mr. **Gilles**. Mr. Abdnor, I am not a toxicologist. I am a biochemist. I guess I will have to defer.

Senator **Abdnor**. Could any of the gentlemen at the table answer that?

Mr. **Gilles**. No; we seek the counsel of EPA in that degree.

Mr. **Helms**. When talking about citrus, I think there is another important issue here that the subcommittee perhaps should be aware of or be interested in. That is that much of the fumigated citrus coming into this country, or fumigated in this country winds up in California. As an example, the citrus that we buy in the stores here in Washington in all likelihood is not fumigated. All citrus from Mexico coming into this country is fumigated, but a large part of that goes to California. Florida and Texas citrus is fumigated only if it goes to California or to Arizona.

So what I am saying is that there is a geographical distribution of fumigated fruit. If I recall correctly, in EPA's analysis of the EDB problem, as an example, the risk to the California consumer was much greater than it was to consumers throughout the rest of the nation, simply because they are not exposed to fruit that has been fumigated with EDB.

It is very difficult to answer your question of what is an acceptable level because where are we talking about? I would certainly not propose one level for California and one level for Florida and another for the rest of the country. That is EPA's responsibility through risk assessment. I can't tell you what, Senator, an acceptable level is. It is not USDA's role. But we are certainly interested in any level that might be set, and that it is accompanied by a very valid in-depth risk assessment to indicate anything above that level would in fact be harmful to consumers.

Senator **Abdnor**. Let's go back to grain. I know a little more about that than I do citrus fruit. Let's say a level is set low enough so it affects a great many bushels of grain throughout the country, through no fault of the farmer. At least up to this point nothing had ever been said or any prohibition been put on this spray. Do you think they should suffer the economic results of it?

Mr. **Gilles**. No, sir. I certainly think that the people who have used the fumigants appropriately in the past and, who might have grain in their possession now, should not adversely be impacted by any of these types of decisions. I believe that all of us in this room are concerned about making sure that the food supply made available in the United States is at a very high purity level, and we would not knowingly contaminate our food in any way.

Previous testimony submitted this morning suggests that in the case of grain, irrespective of what the level of EDB in the grain is, that grain is not consumed as grain, as you would feed it to an animal. Rather, grain is processed and then cooked, and generally about 90 percent of the EDB is dissipated in each of those steps.

So if I were just to give a personal guess, I think that the grain industry could very well tolerate and the rest of the United States would not be adversely impacted if a level of 0.5 parts per million would be used for grain.

Senator **Abdnor**. I appreciate that. That is very reasonable to me, too. But I am glad to hear someone else think that.

Thank you, Mr. Chairman.

Senator DURENBERGER. Thank you very much.

I thank the witnesses. I appreciate your being here very much.

Let me now call Mr. Ron D. White, assistant commissioner, Texas Department of Agriculture; and Mr. C. H. Van Middelem, who is the director of the Division of Chemistry for the Department of Agriculture and Consumer Services in Tallahassee, Fla. I welcome both of you gentlemen. I am sorry about this, but we seem to have a lot more witnesses and a lot more questions than we probably should have, given the time. If you could keep your oral statements 5 minutes or less, it would be helpful. We will certainly guarantee you that your full statements and any material you brought with you will be made part of the record of this hearing.

We will start first with Mr. White.

STATEMENT OF RON D. WHITE, ASSISTANT COMMISSIONER, TEXAS DEPARTMENT OF AGRICULTURE

Mr. WHITE. Thank you very much, Mr. Chairman.

Mr. Chairman, members of the committee, my name is Ron White. I am assistant commissioner, Regulatory Division, of the Texas Department of Agriculture.

Concern over ethylene dibromide is not a new issue in Texas. Since 1980, Texas has had in operation a sterile fruit fly program that has reduced by more than 80 percent the amount of EDB used to fumigate citrus. The concern in Texas was not only over the health effects of EDB but also over the expense of using the product. The sterile fly program saved our citrus producers over $500,000 last year alone.

For the 1983-84 season, suspending the use of EDB will have no effect on the Texas citrus industry. There will be no effect since there is no more fruit to be shipped from Texas because of the severe freezes that have occurred in the past month. There is likely to be permanent damage to our citrus industry from these freezes, and land which is now in citrus may well be shifted to other crops. The latest information we have is that perhaps as many as one-fourth of the trees have been killed by the freezes. All this, and the coldest part of the winter is still ahead of us.

Immediate suspension of use would have only small effect in the near future as well because of the success of the sterile fruit fly program. Developed by the Texas citrus industry, with the help of Congressman de la Garza, the Texas Department of Agriculture, USDA, and others, this program controls fruit flies through the release of sterile Mexican fruit flies along with a careful program of insect trapping and fruit cutting. This program leaves EDB for the last resort, and last year, for example, 98 percent of the fruit was shipped without fumigation. In short, this program succeeded in displacing more than 15,000 pounds of EDB, saving our growers about $500,000 in fumigation costs; and, even more important, reduced health risks to workers and consumers alike.

This program works because we have an agreement with California and Florida, monitored by the USDA, callinp on us to trap flies, cut fruit, try to find larvae, and release sterile flies on prearranged schedules to keep the fly population in check. The program was modified this year, based on USDA experimental data, to include a provision which calls for malathion to be sprayed in areas immediately adjacent to insect finds. Everyone wanted to get by without EDB this year, for both cost and health reasons.

Whether or not we would have made it is a difficult question to answer since the freeze has completely destroyed the citrus crop. But I believe it could have been done. By carefully selecting fruit which was to have been shipped to California and Florida from parts of our growing area which did not have flies, I think it could have been accomplished. This would have been the second year in which we would have had a very abundant crop, and that enters as an important issue because we do have some problem with fruit being left on the trees or on the ground in the groves, providing a habitat for the fly. In short, we have a need to improve the cultural practices of some growers as well. TDA was considering actions, in meetings with our growers, when the freeze came and made such activities moot.

Late last year, our concern over EDB expanded to include a variety of grain-based products on grocery shelves. The Texas Department of Agriculture tested over 100 grain-based products and discovered EDB residues over 1 part per billion in about one out of every three products tested.

We began our testing process immediately after Florida announced its test results. I was, frankly, very surprised to read in my Saturday morning paper on December 10 of the levels of EDB residues discovered in grocery products being sold in Florida, especially considering earlier assurances that EDB dissipated rapidly and would not show up at the grocery store.

I was additionally concerned to learn that the food manufacturers said they intended to sell in other States the products removed from the shelves in Florida. I made a note right then to check into this, and then on Monday after that Saturday we started our tests.

There are two points to notice in the test results from Florida and Texas. The first is that one out of every three products tested contained EDB residues higher than 1 part per billion, with residue in one product, Duncan Hines bran muffin mix, reaching 436 parts per billion. The second point is that at least two out of every three products tested reached the shelves at a competitive price free of any EDB contamination, proving not only that it is possible to get an EDB-free product to market but that the great majority are already getting to market without this chemical.

Our tests in Texas also determined that contrary to some claims, not all EDB residues dissipate during the cooking process. At the request of the Environmental Protection Agency, we conducted cooking tests on seven products and discovered that some EDB residues remained in three of those products. Our testing process is continuing, and we are currently gathering samples of grain-based products being used in school lunch programs across the State.

The results of these tests have met overwhelming interest from the public in Texas. We received over 2,000 telephone calls from individuals seeking to avoid products containing EDB. We provided them with lists of our test results, and our test results were printed in newspapers throughout the State, while at the same time we cautioned the public that EDB contamination in grain products is not brand specific.

Senator **Durenberger**. Are you getting somewhere near the end of your statement? I think we have gone past the 5 minutes.

Mr. **White**. Yes. It did not help that we reassured the public at each opportunity that the risks associated with EDB develop over a long period of time. The public was quick to remind us that this chemical has been used in their food already for more than 25 years and that its carcinogenic effects have been documented for more than a decade.

There is also a larger question here that I want to address. Next year at this time there may well be another hearing just like this about another pesticide. There is no reason to think it won't happen because there are a lot of pesticides now in use which have never had the proper scientific work done on them. These products were grandfathered into the system, and the scientific work which supports their use is to varying degrees inadequate. This problem has been smouldering at EPA for a number of years. Unfortunately, when the fire breaks out, it doesn't happen at the EPA headquarters in Washington; it explodes in Texas, in New Jersey, in Florida, affecting citizens who believe the products to be safe when used according to EPA-approved directions.

Last August a farmworker died in Texas from acute dinitro poisoning. The active ingredient is dinoseb, a chemical that has been around a long time. Some of the data supporting its continued registrations was done by IBT. The label, which had been approved by EPA, did not contain warnings about protective clothing and contained misleading medical advice, which cost that man his life.

Texas does not have, nor does any other State, the resources to handle registration. But EPA has never taken it seriously, in my judgment, and people who use these products are being exposed to unknown risks and some of those risks are very large indeed.

Two things are needed to be done to correct this problem. First, you need a commitment from EPA to organize its activities to get the work done. Second, you have to give them the resources they need to accomplish the task.

Failing this, you never know just when the next screamer is going to arise. There are a number of candidates out there. There is a real backlog of scientific work to be done. This work will only be accomplished by a plainly written amendment to FIFRA that sets a nonnegotiable timetable for accomplishing the necessary work and which provides sufficient funding to get the work done.

In conclusion, Mr. Chairman, I just want to reinforce the notion that the people I have talked to about this are indignant, and they are not in any sort of a panic. They want EDB out of their food and they want to see something put in place that will prevent the sort of a spectacle they are witnessing from ever arising again. I do not believe that is too much to ask of Government. We at the Texas Department of Agriculture have done everything within our power to get EDB out of the food supply, but it is a national problem. You cannot legally buy EDB in Texas today, but you can buy cornmeal or flour or muffin mix that is contaminated with EDB.

We stand ready to help you, EPA, and anybody else who wants to get this fixed.

Senator **Durenberger**. Thank you very much for your testimony. Dr. Van Middelem.

STATEMENT OF DR. C. H. VAN MIDDELEM, DIRECTOR, DIVISION OF CHEMISTRY, FLORIDA DEPARTMENT OF AGRICULTURE

Dr. VAN MIDDELEM. Mr. Chairman, I am going to present only portions of the written testimony that has been previously submitted by Commissioner Doyle Conner, who regrets that he could not attend this hearing today.

My name is Charles H. Van Middelem. I am director of the division of chemistry in the Florida Department of Agriculture and Consumer Services. I want to thank you for the opportunity to appear before your committee and to share with the committee Florida's recent experiences with ethylene dibromide.

Early in July 1983, after news of recent findings of trace quantities of EDB in ground water in the State of California, the first drinking water samples were drawn by department of agriculture and consumer services personnel. These were collected and analyzed in our laboratory at Commissioner Conner's request, even though the primary responsibility for ground water does not come within the purview of the department's authority to ascertain if any EDB residues were occurring in drinking water wells close to areas known to be treated with EDB in Florida.

The initial analysis of one of these samples appeared to be positive and was subsequently confirmed. Following the detection of EDB in a number of drinking water wells, the Florida Department of Health and Rehabilitative Services suggested that the users of water from these wells containing EDB levels in excess of one-tenth of a part per billion should seek alternative sources of drinking water. This action by the department of health was dictated because of the absence of a Federal tolerance for EDB in drinking water. Consequently, on September 16, Commissioner Conner issued a temporary suspension on the distribution, sale, and use of EDB as a soil fumigant in Florida. The temporary suspension was followed by a permanent suspension on October 7, 1983.

I might add, in the past 6 months, between the Florida Department of Health and the Florida Department of Agriculture, and Consumer Services, almost 3,000 water samples have been analyzed in Florida.

The discovery of trace quantities of the parent compound EDB in drinking water caused concern among personnel of the Florida Department of Agriculture, and we began to look at food items under the provisions of the Florida food law. Department personnel began to review federally registered uses of EDB which may have an adverse impact on the food chain.

Since EDB is federally registered for spot fumigation of grain mill machinery and for fumigation of stored grain, a sampling and analytical program was initiated by this department to randomly survey processed grain products and food products derived from animals which may have ingested grain fumigated with EDB.

In September, the first samples of food products were analyzed by departmental personnel for possible EDB residues. During the next several months a total of 92 food and feed product samples of various types were analyzed. Only one cornmeal sample and one wheat grain sample appeared to contain any traces of EDB, or less than one part per billion.

As a result of the detection of trace levels of EDB in the cornmeal and wheat samples, we began to intensify our efforts in looking for EDB residues in processed grain products, particularly corn products at that time. In the next month, an additional 53 products were collected and analyzed, including 29 additional samples of corn products on which analysis and confirmation were completed during the week of December 5; 14 of the 29 corn product samples contained EDB residues in excess of one part per billion.

On December 5 Commissioner Conner notified the Federal Food and Drug Administration by mailogram of our preliminary detection of EDB in a number of cornmeal, cornbread mix, and grits samples. In the absence of established Federal tolerances for EDB per se in processed grain products, FDA was requested to advise us of their regulatory strategy in this situation. A copy of the mailogram was sent to region IV office of the EPA and, at the same time, an ongoing dialog with representatives of the department of health in the State was initiated.

On December 8, we received FDA's response which advised that FDA could pursue regulatory action only if inorganic bromide residues exceed the established tolerances. In order for them to consider regulatory action on the basis of the parent compound EDB, EPA would have to establish new EDB tolerances following revocation of existing regulations.

On this same day, December 8, Dr. Stephen King, Florida's State Health Officer, recommended to Commissioner Conner that foods contaminated with EDB at a level equal to or more than one part per billion should not be consumed by the public. On December 9, based on this recommendation, and after two joint meetings during the day between representatives of the Department of Agriculture, Department of Health, and the affected industry, we initiated our first stop sale action ordering removal of 13 corn products from the marketplace.

During the ensuing weeks, as samples were selected and analyzed and confirmed, the Department issued four additional stop sale orders. These actions occurred on December 15, December 20, 28, and January 10, 1984. As of January 10, 1984, a total of 77 corn and flour products had been identified for removal from the marketplace. These samples included grain products from 36 different companies.

On December 21, 1983, a joint letter to Mr. Ruckelshaus, EPA Administrator, from Governor Graham and Commissioner Conner urged that EPA act expeditiously in establishing current and relevant Federal standards for EDB in foods. The Governor and Commissioner Conner pointed out that the EDB problem was not Florida's alone but one of national proportions because the majority of grain products found to be contaminated were imported into Florida from other States.

Subsequently, Governor Graham received an interim response from EPA in which they shared our concern and agreed that EPA should use its scientific and technical resources to carefully examine the EDB problem.

Senator DURENBERGER. Are you near the end?

Dr. VAN MIDDELEM. Yes, sir.

Senator DURENBERGER. Great.

Dr. **Van Middelem**. On December 29, representatives of the Florida Department of Agriculture and the State Health Department met with EPA officials from Washington to share Florida's most recent analytical results and to encourage them to establish interim guidelines for EDB in foods that could be used uniformly by all States. As a result of this meeting, EPA told Florida officials that EPA would recommend how much EDB residue would be allowed in food and would attempt to make this recommendation by the end of January 1984.

Mr. Chairman, in conclusion, we are most appreciative of the interest of your committee, and I will be pleased to respond to any questions the committee may have.

Senator **Durenberger**. Thank you both very much.

Earlier in the day we were talking to EPA about their efforts. I asked a question about the number of employees in the Pesticides and Toxic Substances Division 3 years ago versus today. The number was 128 then and it is now 20. Along the line that you were suggesting, Mr. White, relative to the need for EPA resources having to be applied to this problem, is the number itself something we ought to be concerned about? Can 20 people do a great job at the EPA? I guess they are going to put on another dozen or two. Is that the extent of the resource needs that might be needed in EPA?

Mr. **White**. No. That doesn't really begin to deal with the question. Senator, there are 600 active ingredients more or less on the list of products that need to be reregistered. It is a good question as to how long it is really going to take to do each one of those. But we are talking about 600 active ingredients that need to be reregistered. You are talking about 20 or 40 people. You are clear out of the ballpark.

Senator **Durenberger**. One of the things we have been beating on here over the last year or so is trying to get a little more help from the people putting the chemicals on the market. It would be helpful to the process. Not all of the work in assessing exposure levels and risks and so forth has to be done at EPA, I take it. Do you want to make a comment on that?

Mr. **White**. That is true. But someone at EPA has to be there to review the documents. You know, they have had to try to raise workloads at EPA. That is how we got into the cut-and-paste problem on review. You are just asking them to do too much with what they have.

Senator **Durenberger**. Dr. Van Middelem, you heard me read off here a little while ago when Senator Abdnor was asking about parts per billion, and I read off some pulp tests on Florida grapefruit over in California. Does that sort of thing concern you at all? I know you don't live in California. Is that kind of exposure level kind of high?

Dr. **Van Middelem**. Of course we received these analytical resutls only fairly recently from California although fruit sent from Florida to California has been fumigated for a considerable period of time. I should emphasize the fact that California has previously required that Florida fruit transported into California be treated with EDB and, therefore, Florida has been complying with previous California requrements. Japan still requires EDB fumigation of imported Florida fruit. I think the EDB levels would depend considerably on how long the fruit had been out of the shipping box, because EDB, as you already heard, will volatilize to a considerable extent when exposed to air. I would think, while the unboxed fruit remains exposed to air in the retail store, that the EDB residues would diminish quite rapidly. When the fumigated fruit comes right out of the shipping box immediately after arrival at its destination, the EDB residue levels would be expected to be rather high because there has been no time allowed for air exposure and the volatization process to take effect. But there is apparently some residual EDB that remains in the fruit. Apparently EDB is not getting into the juice. It certainly has not shown up in any of our Florida fruit juice concentrate that we have tested.

Senator **DURENBERGER**. I thank both of you gentlemen very much for your testimony. I wish there was more time this particular day to spend visiting with you. I am sure we will avail ourselves of your services again in the future. Thank you very much.

Our final panel includes Ms. Deborah Berkowitz, director of safety and health, Food and Allied Service Trades Department, AFL-CIO; Ms. Suzanne Kossan, industrial hygienist, International Brotherhood of Teamsters; Ms. Ellen Haas, executive director, Public Voice for Food and Health Policy; and Mr. Jay Feldman, national coordinator, National Coalition Against the Misuse of Pesticides.

We will go in the order of introduction. I would ask you to try to keep your statements to 5 minutes, if you can. All of your comments and any other material you want to make part of the record will be made part of the record.

We will start with Ms. Berkowitz.

STATEMENT OF DEBORAH BERKOWITZ, DIRECTOR, SAFETY AND HEALTH, FOOD AND ALLIED SERVICE TRADES DEPARTMENT, AFL-CIO. ACCOMPANIED BY AL MEYERHOFF, NATIONAL RESOURCES DEFENSE COUNCIL

Ms. **BERKOWITZ**. Thank you, Mr. Chairman.

I am Deborah Berkowitz, director of safety and health for the Food and Allied Service Trades Department of the AFL-CIO. We represent 45,000 grain elevator and mill workers, many of whom live in the State of Minnesota and throughout the United States.

I have here with me Al Meyerhoff from the National Resources Defense Council.

Last week the AFL-CIO and the National Resources Defense Council submitted a letter to EPA. Al will give a very short statement at the end of my very short statement on EDB. Al is also a resident of California. It seems to me they might have the most to worry about.

Before I begin my statement, I am going to paraphrase it and hope to have the whole thing submitted in the record, I just want to make two points. One is that EDB is still being used on grain in this country. Our grain elevator workers in the export ports of Duluth have found cans of EDB containing fumigant on the grain coming into their elevators. It is still being used. That grain is coming from Minnesota, North Dakota, and South Dakota. So without an emergency ban, I submit to you EDB will remain on the market.

Another point I want to make, the gentleman from the Federal Grain Inspection Service talked about the process of grading grain, which they are responsible for, and I just wanted to add one point. That is that the only way by law right now that workers, for instance in Duluth, or Superior, Wis., where there are export ports for grain, can test, is they must stick their noses into a sample of grain and smell it for mold.

Now the GMA has submitted some data to the EPA on the kinds of concentrations in the grain before its milling. There are contaminations as high as 16,000 parts per billion in the corn that is being delivered from the elevator to the mills. These are the kinds of concentrations that my members have to stick their noses into the grain and smell it. I submit to you that I know workers don't-count for everything in the world, but there are 100,000 grain elevator workers out there.

Senator **Durenberger**. Can you smell it without inhaling it?

Ms. **Berkowitz**. You cannot smell EDB until the concentrations are 10,000 parts per billion, which is about a hundred times higher than the safe levels recommended right now by OSHA.

Now I will proceed with my very short statement here.

The grain element and mill workers we represent are somewhat like canaries that miners brought down into the mines to test for deadly gas. The experience of our membership with EDB leads us to believe that from one-half to three-quarters of this Nation's 250,000 grain elevator and mill workers may have been exposed to dangerous levels of this chemical. Despite the availability of substitutes and despite the growing list of EDB victims in the workplace, neither the Government nor the industry has moved to take action.

I implore this subcommittee not to let the problems of pesticide regulation fade from your memory when and if EDB has finally been controlled but to begin to take steps to assure that the process of protecting the public from poisons will never again become victim to Government malfeasance. Our laws governing the use of pesticides may indeed be a serious culprit and may need reworking, but the last 3 years of complete regulatory silence despite mounting evidence of danger must be held accountable.

I have submitted as an appendix of my testimony a chronological history of what we call the inaction that starts with the 1974 National Cancer Institute Memorandum of Alert on the dangers of EDB and traces it through the 1981 statement by the agency's scientists at EPA that EDB is the most carcinogenic substance ever tested by the National Cancer Institute, to the 3-year halt in all protective regulatory activity by OSHA, USDA, and EPA, despite meetings with these agencies where they said they would be moving in a matter of months, to the inadequate, loophole-ridden cancellation order meted out this fall by EPA that has already become victim to interagency squabbling as it has been challenged by the Department of Agriculture. And the State of Florida has come in to contest it.

What we are dealing with here is a system that needlessly left a chemical on the market, a chemical with available and cheaper substitutes, a chemical that may be the most carcinogenic substance ever tested by the National Cancer Institute.

I just want to give a brief look at the grain industry.

Senator **Durenberger**. You said brief four times already. I am going to have to terminate the whole hearing at 12:30, so either you terminate your statement now or no one else will get a chance.

Ms. **Berkowitz**. Just one point very briefly.

Senator **Durenberger**. That is the next time you said briefly. Why don't you just submit the rest of your statement.

Ms. **Berkowitz**. There are two substitutes now being used on the grain industry. They are very widespread. Those substitutes are probably the more popular chemicals on the market for grain. The substitutes, however, do contain carbon tetrachloride, 80 percent. I would submit this is just something the committee might want to look at. Eighty percent of the fumigants used on grain are carbon tetrachloride. Those are the ones that are going to be used heavily now.

In the milling industry, they have stopped using——

Senator **Durenberger**. I am going to end your testimony. I am sorry.

I am going to ask for the next witness, Suzanne Kossan, please.

Ms. **Berkowitz**. Al Meyerhoff has a brief statement.

Senator **Durenberger**. We will give Al a minute at the end. I apologize for doing this, but I am now undertaking this all by myself. I am into my fourth hour. Your testimony can get into the record. We don't have to spend a lot of time listening to you deliver it in public.

Suzanne.

STATEMENT OF SUZANNE KOSSAN, INDUSTRIAL HYGIENIST, INTERNATIONAL BROTHERHOOD OF TEAMSTERS

Ms. **Kossan**. Thank you. My name is Suzanne Kossan. I am from the International Brotherhood of Teamsters.

In the interest of time, I won't get into the toxicity of EDB. I think that the record on that is clear. I just would like to underscore the citrus issue because we heard a lot of talk about grain this morning, but I think the citrus issue is of vital importance also. We have submitted this for the record.

We would just like to underscore the fact that in October 1981, FDA and EPA were both well aware that there were significant EDB residues in foodstuffs, in both grain and citrus, and in fact we have submitted for the record the correspondence between FDA and EPA showing 98 percent of the citrus fruit tested had detectible levels of EDB, and 56 percent of this 98 percent were levels in the area of 250 parts per billion, and 10 percent of those tested had a level of above 3,000 parts per billion. They took no action in light of all of that knowledge. They took no action.

They promised us on December 22, 1981, that they would set a residue level within a few months. A few months become a few years. We still have nothing. And recent studies out of California, 1984 data, show that the EDB problem persists in foodstuffs, particularly in citrus. There are residue levels in citrus as high as

16,500 parts per billion in the peel and 1,420 parts per billion in the pulp.

This poses a particular problem not only for consumers but for the people that we represent, the workers, because all of that residue that is available in the peel is available for off-gassing. That is what our people are inhaling on docks and warehouses and at the retail level.

We are looking for some action on EDB. We would like to see EPA set residue levels. We would also like them to totally ban the chemical. They made an attempt to regulate EDB on September 1, 1983. We thought it was a weak attempt. Their cancellation orders on grain and citrus were immediately challenged by the industry. They have been stayed. That is a 2- to 3-year process in trying to resolve those cancellation orders.

As I said earlier, we would just like to see some immediate action on what we consider to be a considerable risk to our people.

If I have a few more moments, I would just like to state that there are alternatives to EDB. Currently major grain companies have voluntarily suspended the use of EDB on grain. Florida and Texas have agreed to California's request to fumigate citrus going into California with other pesticides. Irradiation will be used commercially on papayas and mangos and tropical fruits from Hawaii as a result of a joint venture between Irradiation Technology, Inc., and Hawaiian Tropical Fruits, Inc. Irradiation is currently used in 28 countries, including Japan, the Netherlands, and Canada. Other possibilities for alternatives include cold treatment, heat, and low oxygen environments. So clearly EPA can ban EDB for citrus and tropical fruits to force the use of these alternative technologies.

Thank you.

Senator **Durenberger**. Thank you very much.

Ellen Haas.

STATEMENT OF ELLEN HAAS, EXECUTIVE DIRECTOR, PUBLIC VOICE FOR FOOD AND HEALTH

Ms. **Haas**. I am Ellen Haas, executive director of Public Voice for Food and Health Policy. I will try to give my statement in the 5 minutes.

Senator **Durenberger**. It bothers me a great deal, too. I can't put you at the beginning where I would like to have you. I go through this in all the other committees. But there is some kind of a stupid rule around this place that says administration witnesses always go first and the people with the problems and the solutions always go last. I just want to share that frustration with you.

Ms. **Haas**. I certainly appreciate that. I think it is important to condense these comments which are in the most serious vein because the consumer is the one at the end of this whole food chain who is bearing the risk and will continue to bear the risk until we resolve the EDB problem.

The case of EDB is a classic example of agency inattention to consumer and environmental hazards and prolonged use of a chemical pesticide which should have not been registered in the first place and which should have certainly been removed from the market a long time ago. In order to minimize further risk from this lethal chemical, we believe it is imperative for the EPA to move quickly—and quickly has not been the way it has been going—to cancel the remaining uses and establish legal tolerances. In order to minimize the potential for future EDB crises, our testimony includes statutory recommendations for changes so that we move to better the ways that pesticides are approved and residues are regulated.

We were deeply disturbed by the September announcement that the agency did not move to cancel other registrations besides soil fumigation on an emergency basis, and especially that it has refused to set a tolerance to date for residues of the chemical on consumer food products.

As we know, this history, as Debbie has mentioned, is one of inaction, and we have known for some time about the strong cancer-causing effect of EDB. Through the regulatory process in the late 1970's, the sponsors of the pesticide were given the opportunity to present evidence supporting the continued use of EDB. But by December 1980 the EPA announced the presumption of carcinogenicity had not been rebutted. These are the words back then in 1980: "the risks to human health of certain uses of EDB are greater than the social, economic, and environmental benefits of these uses and that risk reduction measures cannot reduce the risks to an acceptable level."

By far and away, this 3-year hiatus, the time between 1980 and 1983, is the most objectionable and troublesome element of the entire EDB regulatory process. Whether because agency staff was reduced, as we heard in such a dramatic way, or industry pressure was exerted, as we all know it must have been, it doesn't matter. The fact is the agency has allowed the public to be placed at significant risk of cancer and other diseases for an unnecessarily long period. We believe the risk has been great enough for long enough and that it is time to rid the environment and the food supply of this lethal pesticide.

We strongly believe that a number of steps must be taken to minimize the contamination problem and expedite removal of the pesticide from the food supply. At the same time, however, we hope that Congress will consider the needed changes in the statutes which are supposed to protect the consumers and public from hazards.

We believe the EPA must issue an emergency suspension of the registration for use of the pesticide as a post-harvest fumigant of grains and citrus products. For the grain uses, it is not at all clear why the EPA has not already taken action to cancel registration. It is equally important in the citrus area.

The EPA itself has concluded that the general public may typically face significant increases in cancer risks from treated fruit. According to the risk assessments done by EPA, it is estimated that there would be at least 4,400 additional lifetime cancer patients in the United States. The risk assessments are still an unrefined mechanism. They are indicators of such risks.

Let me say, too, you talked about how much contamination. The FDA in the 1981 study found enormous concentrations of the pesticide on citrus fruit. Ninety-eight percent of the products contained measurable residues and over 40 percent had residues over 250 parts per billion. Ten percent were contaminated with levels of EDB in excess of 3,000 parts per billion.

The industry maintains there are no practical alternatives, but as we have just heard, cold storage is certainly one that should have been moved on long ago. In fact, the EPA has estimated that the industry cost for moving in the cold storage direction would be approximately $25 million to the industry.

Senator **DURENBERGER**. Are you right near the end?

Ms. **HAAS**. Yes, getting there.

The agency must, in addition to canceling registrations of remaining EDB uses, quickly move to set tolerances for residues of EDB.

Let me say in closing, because I think it is important, I think you have the facts in my testimony, you have the facts from this panel, but I would like to say that after this hearing there are still four important questions that have not been answered, that I think remain, and I am disappointed after hearing these 4 hours that we have not heard the answers.

Why has it taken 3 long years for the EPA to act on the registration for soil fumigation, to act at all? Why was the exemption for the tolerance not revoked at least as of 1977 when the EPA issued its rebuttal? Why does the agency or FDA have no comprehensive data after all this time on consumer exposure to the chemical. The factor that has been cited by the EPA is the reason why it is difficult to set a tolerance. Fourth, how can the EPA—and this is a new question, and I am looking toward the future—permit the use of such alternatives to EDB as methyl bromide or carbon tetrachloride when these substances are suspected carcinogenic and toxic, but when the EPA again has no data as to how great such chances are and how great residues remain.

These critical gaps in knowledge and inaction over these past years by the agencies charged to protect the public health show clearly how inadequate even dangerous current food protections are.

I thank you.

Senator **DURENBERGER**. Thank you.

Mr. Feldman.

STATEMENT OF JAY FELDMAN, NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. **FELDMAN**. I guess I should say good afternoon. I was ready to say good morning. I guess I am also in the venerable position here of wrapping up the day and providing all the answers to Ellen's questions.

What strikes me, having followed pesticide issues for many years now, is that at issue here is the fact that the regulatory program of regulating chemicals, of regulating pesticides in particular, has entered the political arena. We see that time and time again, in pesticide after pesticide. In fact, when people heard Mr. Durenberger was holding a hearing here today, they said, "Oh, he is not up for reelection so it is appropriate to do." In fact, that is precisely what we are struggling with in Congress today, to answer the questions, to sort out the scientific facts that you have had presented here before you today. You are seeing I think a sense that these questions are answered or forced to be answered in the political arena. As a result, you see a tremendous amount, or at least my interpretation is we see a tremendous amount of corporate power focusing on these questions and a tremendous amount of agency vulnerability to that power.

As a result, we have moved forward with a proposal in specific legislative terms. Mr. Proxmire outlined it. We are in support of his proposal. The attempt there is not only to rearrange incentives within the national pesticide control law to insure that pesticides are brought into compliance with modern safety standards, modern scientific standards, but to insure that the conflict of interest that exists today is done away with, that the regulated industries don't tell EPA how they think they should be regulated, that the concept of decisionmaking under the rubric of the art of the possible—that is, we decide and make political decisions within the art of compromise, which we all understand—is not applied to chemicals.

The American public I don't believe is willing to accept the fact that they must in 1984 meet a carcinogen halfway. It is just not something they are ready to accept. The programs we have proposed in our written statement are specific and we, of course, endorse the sense that we have to deal with the immediate EDB danger, deal with the crisis, purge the pesticide from the food supply, prevent the entry of this pesticide EDB into the marketplace, and also deal with the question of the tainted water or contaminated water. I noted today, that although many have noted the fact that water is contaminated with EDB no one is talking about a clean-up program——

Senator **Durenberger**. We will get to it. We have a lot more time to work on this.

Mr. **Feldman**. Good. I appreciate that and would like to work with you on that. But the fact of the matter is we do have people, as you know, across this country today drinking water contaminated with EDB. That must stop, and that must stop immediately. My sense is it will demand some level of involvement from Congress because this administration, it appears, is not equipped or ready to move on this question.

The other thing I think we need to sort through quite carefully are the facts. Perhaps the hearing record today will help to sort that out. The Grocery Manufacturer's Association in presenting their testimony today is wrong. The EPA had information on finished product residues back in 1980 when it issued its preliminary decision to cancel, and on and on and on. I just note that being one example. The article in the Journal of the Officials of Analytical Chemists is an indication that there are some factual discrepancies that I hope you can sort through. Having done all that, I think you will find that the alternative, as EPA has proposed in many of their documents, is one that serves both the consumers and the farmers.

I end on one note here. I have found in this very controversial work it seems on pesticides that the divisions that seem to be created in public view are not necessarily divisions that operate in the real world. That is, the users of pesticides have much in common with the consumers of pesticides. The problem is the regulatory framework and the statutory framework have allowed the users of pesticides and those involuntarily exposed to pesticides to be misled about their safety. And until we correct this deficiency in law so as to insure that products are fully tested, we will continually, as was stated by the Representative from Texas, be back here year after year. It may not be EDB. It may be permethrin, another pesticide which hasn't come into public focus. But we will be back here. Let's stop that process and get an approach that we can use.

Thank you.

Senator **DURENBERGER**. Al, I guess you picked up a minute from the Teamsters and a minute from Jay. You can take what you need to elaborate on your point.

STATEMENT OF AL MEYERHOFF, NATIONAL RESOURCES DEFENSE FUND

Mr. **MEYERHOFF**. I only need a minute.

I think there is one conclusion that can be drawn from this hearing. That is the problem isn't just EDB. It is EPA. There is general agreement even among the industry scientists that testified that EDB is a potent carcinogen, it is a mutagen, it causes sterility, reduced sperm count, and it is a very deadly chemical. We are not dealing here with saccharin. On a 1 to 10, this chemical is a 10.

The only debate is how much is too much, what is a safe level. I submit that is not a scientific question. That is a policy question. We have a law in the United States that is rooted in science and policy that says that until the scientists can agree, no detectible level of this chemical should enter the American food supply.

I would like to also comment on EPA's position here this morning. In my judgment, EPA is attempting, and the Reagan administration is attempting, to use the exemption that was improperly granted as a shield to prevent any effective action by the American public. They are attempting to pass the buck to the States.

We have submitted a letter, which I would ask be submitted on behalf of the AFL–CIO, advising that they do not ban this chemical on an emergency basis and set an immediate tolerance that will assure no detectible residues in the food. If that action is not taken soon, we will issue a suit.

I would like to also make a comment on alternatives like carbon tetrachloride. Carbon tetrachloride is much more widely used on grain than is EDB. I believe the mixture is about 80 percent carbon tetrachloride and carbon disulfide about 10 percent. Carbon tetrachloride is also a powerful carcinogen and mutagen.

We have submitted to the staff of the subcommittee a draft of the EPA health assessment on carbon tetrachloride. We found residues of carbon tetrachloride on dairy products, meat, oil, beverages, fruits, baked bread, fish, seafoods, and on other products.

Last night I looked up the tolerances for carbon tetrachloride in Federal regulations. There is no tolerance. Carbon tetrachloride has also been granted an exemption.

Methyl bromide is also being used now in Florida as an alternative to EDB on oranges coming into California. It is very close to DCPB and ethylene dibromide. We used EPA to obtain the health studies on them. I called my scientist about the health studies.

There are no cancer sites on methyl bromide, no neurotoxicity. We have gone from one chemical we know is a carcinogen to another chemical there is good reason to believe that there is no data on at all. Yet that is now coming into the food in California.

I would like to sum up with one other reference to IBT that Senator Proxmire mentioned. There are 23 tolerances set for chemicals in our food supply in the United States with a pivotal study, that is cancer and birth defects, done by IBT. That is fraudulent data, invalid data. EPA fails and refuses to act against those tolerances, we think illegally.

The end of all this is the real problem is the law, the statute. It invites industry bias. It invites closed door meetings, which brought us here today. It was written essentially by the chemistry industry.

In a few days the Reagan administration will be stating its position. I think their position will indicate whether the changes at EPA are real or illusory.

Senator **Durenberger**. I want to ask one question, and probably two of you can respond to it, that we haven't really gotten into, another one I guess we haven't gotten into in depth, and that is the occupational safety problem.

Recently OSHA has made some proposals on reduction of exposure levels. But I would like perhaps first from the Teamsters, because you did bring it up, and then AFL-CIO, just a little bit of history or a little bit of observation about what the nature of the problem is and how difficult it has been to bring some of those concerns to the attention of the Occupational Safety and Health Administration.

Ms. **Kossan**. We had a similar experience with OSHA as with EPA. The Teamsters petitioned OSHA in 1981 for an emergency standard on EDB use, and they denied our petition. They said they would participate in expedited rulemaking. Well, expedited rulemaking took a couple years. Finally in October of this year we did see OSHA propose a regulation on a permissible exposure limit for EDB. Unfortunately, the level that they proposed is not adequate.

Senator **Durenberger**. The one I referred to is not adequate?

Ms. **Kossan**. Yes. The proposal of 100 parts per billion we feel is inadequate. Our in-house risk assessment shows that at that level, we will still have 9 cancer deaths per 1,000 from continuous exposure at that proposed level. That is still highly unacceptable to us.

There will be hearings in the beginning of February on OSHA's proposal. We hope to be able to persuade them that what they have done is not adequate. But we have had quite a struggle over the past 3 years with OSHA also on this. There is an incredible reluctance to do anything with EDB. We think that basically special interest politics have blocked the regulation, particularly the citrus industry, and the grain people.

Senator **Durenberger**. Miss Berkowitz?

Ms. **Berkowitz**. One thing is when OSHA turned about the request for a standard which the AFL-CIO proposed in 1981, the National Institute of Safety and Health pleaded with Mr. Octer, the head of OSHA, to reverse that decision, saying that EDB was a carcinogen, and nothing happened for 3 years. OSHA's standard on grain and the flour industry would require the workers to wear respirators to protect them. The position of the grain millers is only an emergency suspension of the use of EDB on grain and flour and use on equipment in flour mills would protect workers and not a standard that would require every mill and grain worker to wear a respirator.

Senator **Durenberger**. Thank you all very much. I appreciate your testimony a great deal. Thank you.

[Whereupon, at 12:40 p.m., the subcommittee was recessed, to reconvene subject to the call of the Chair.]

[Statements and other material supplied for the record follows:]

STATEMENT OF
JOHN A. MOORE, D.V.M.
ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
WASHINGTON, D. C.
JANUARY 27, 1984

Good morning. I am here today to discuss the pesticide ethylene dibromide (EDB) and the activities EPA has underway to address the concerns raised about EDB residues in a variety of food products.

Let me briefly review the background of the Agency's basic position on EDB which led to the regulatory decisions of September 28, 1983. EDB has been used as a pesticide for over 35 years and has been effective in destroying insects in soil, grain and citrus. As new data on EDB's potential health effects have become available, and as alternatives for most major uses have been developed, the balance between risks and benefits has shifted. Based on these new health effects and economic benefits data, the Agency concluded that the risks of continued use outweigh the benefits and, consequently, that registrations for major uses of EDB should be cancelled. In making these decisions the Agency recognized that there were several distinctions between the major uses of EDB and that different regulatory approaches were appropriate for the uses based on currently available data.

For the soil fumigation use, EPA took the strongest action possible under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), an emergency suspension which immediately halted sale and distribution of EDB products for that use. This action was based on data showing that use of EDB had caused ground water contamination in several states. Soil fumigation accounted for about 90% of the use of EDB as a pesticide. For post-harvest fumigation of citrus and tropical fruits, EPA issued a notice of intent to cancel this use of EDB to become effective September 1, 1984. This phase-out period was intended to allow for commercial introduction of alternatives to EDB fumigation to meet both domestic and foreign quarantine requirements. For fumigation of stored grain and the spot fumigation of grain milling machinery, the Agency issued a notice of intent to cancel this use of EDB effective in 30 days. However, registrants and other interested parties appealed these cancellation notices for the non-suspended uses (i.e. fumigation of citrus, tropical fruit and grain). Non-suspended uses continue, as permitted by statute, during cancellation proceedings.

The September cancellation notices for stored grain and spot fumigation pointed out that more monitoring data were needed to assess accurately the extent to which EDB residues occur in grain and grain-based foods. To assist the EPA, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) conducted further monitoring of various foods to clarify this issue.

In late 1983, FDA's ten regional offices collected 42 samples of milk, bread, baby food and flour. Except for four wheat flour samples, EDB was not detected in these commodities. FDA also analyzed 69 samples of stored and processed grain from 7 facilities known to have used EDB. A majority of these samples had detectable levels of EDB with most positive findings below 50 parts per billion (42 out of 53 positive samples). There were also several samples of this grain with very high residue levels.

USDA provided an analysis of meat samples. Of some 300 samples of beef, pork and poultry, only one pork sample had detectable levels of EDB. These data suggest that EDB residues in livestock and poultry are not a significant source of human exposure.

In December, additional data on EDB residues in foods were collected by a number of states. The State of Florida provided analyses of grain-based food products such as flour, corn-meal and cake mixes taken from store shelves. These findings show detectable residues in roughly one third of several hundred samples. The majority of positive samples indicate residues from 2 to 40 parts per billion. Similar information provided by Texas, Georgia, and North Carolina generally confirm Florida's findings. At least 16 additional states have informed EPA that they intend to conduct their own sampling of food products for EDB residues.

Since many states intend to monitor for EDB residues, EPA has solicited their assistance in focusing on areas where more information is particularly needed. In a letter to all state governors and in subsequent meetings with state agriculture officials, Administrator Ruckelshaus specifically asked for additional data on; (1) raw grain products; (2) processed grain products both as purchased and after preparation according to label directions; (3) grain products such as cold cereals and oils which are eaten without further processing; and (4) other non-grain commodities such as citrus that may be fumigated with EDB. The Agency also asked USDA and the states to provide as much information as possible on the extent to which EDB is still being used today in grain storage and milling operations.

The Agency has been particularly interested in obtaining additional data on the effects of cooking consumer products to determine the extent to which cooking reduces EDB residue levels. The state of Florida analyzed some food products after cooking and found reductions in EDB levels ranging from 78 to 99%. Florida also sent some of their product samples to EPA and we are having further analyses of cooked products done by an independent contractor and by FDA. The Grocery Manufacturers of America, Inc. (GMA) has provided data on several hundred samples of cooked foods including baked goods, hot cereals and pancakes which show the same 78 to 99% reduction range in the majority of samples, although a few samples showed lower reductions.

The Agency is also examining EDB residue levels in citrus to determine if additional action with respect to citrus is needed.

In short, EPA is now in the process of collecting the information necessary to clarify the EDB situation. We will then consider three specific actions: 1) whether to issue emergency suspension notices, in addition to the cancellation notices already in place, for the uses remaining in effect; 2) recommending what residue levels are acceptable in the food supply; and 3) removing impediments to federal enforcement actions by revoking the existing tolerance exemption.

We believe that EPA has adequate authority to deal with the EDB situation and is currently exercising that authority in a responsible manner. The Federal Insecticide, Fungicide and Rodenticide Act provides authority for emergency suspension of pesticide registrations in cases where an imminent hazard to public health is deemed to exist. We are deciding whether the available data supports such a determination. In addition, EPA can recommend action levels for pesticide residues which are the basis for FDA monitoring and enforcement actions. In this particular case the process of setting a federally enforceable standard is complicated by the fact that EDB was exempted from the requirement for federal tolerances for most of its fumigation uses in 1956. We are moving expeditiously in revoking these exemptions and will assist state agencies in their own efforts to monitor and to control EDB residues.

EPA's responsibility is to assess accurately the magnitude of the risk posed by EDB residues in foods so that the Agency can adequately protect public health, without an unnecessary disruption of the food supply. While prompt action is necessary to prevent public apprehension, we will only act based on knowledge.

The available data show that EDB is a toxic chemical. EDB has been shown to be an animal carcinogen by each route of administration by which it has been given (inhalation, gavage and skin painting). EDB was shown to cause cancer in rats and mice, in both sexes and at each dose level in the gavage and inhalation studies. In these studies, EDB was found to cause cancer not only at the primary site of exposure but also at distant sites. EDB has also been found to induce mutations across a variety of test systems using generally accepted test methodologies. These mutagenicity tests provide support for the position that EDB is a directly acting carcinogen.

There is also some concern that EDB may cause reproductive effects. These effects have been demonstrated in a variety of species including bulls, rats, mice and chickens. Human epidemiology studies, however, have been inconclusive, primarily due to limits imposed by small sample size. The results of these investigations show that the principal health concerns about EDB are for chronic effects. Thus, the presence of EDB residues in food needs to be evaluated in terms of levels of exposure actually occurring and the length of time exposure can be expected to continue.

Based on our now larger and more complete data base, the Agency is in the process of recalculating the risks of exposure to EDB. Moreover, since EPA's September order already proposed a cancellation of the remaining food uses of EDB, the Agency is evaluating the additional risk associated with dietary exposure that is likely to occur if EDB use continues during the cancellation hearings, typically a 2-year process. Because the law provides authority to suspend registrations immediately if the risks outweigh the benefits of use during the period of the cancellation hearings, this is one of the issues EPA is addressing.

It should be understood that if EPA suspended the grain uses of EDB today, many treated commodities would remain in the channels of trade for a considerable time. However, we believe that there are certain agricultural practices and manufacturing processes which can reduce residues in treated grain. EPA is receiving information from the Department of Agriculture and the food processing industry which will shed some light on this. Residues in stored grain decline over time, so that current levels may be reduced by extending the storage period or by aerating the grain to allow dissipation of residues. As I stated previously, preliminary information is that cooking can result in very large reductions in residues. Thus, when we consider setting permissable levels it will be with a clearer understanding of what practical measures are available for achieving those levels in existing grain and food products.

In deciding what actions to take, the Agency is also looking at the availability of alternatives to EDB. Alternatives are available for spot fumigation, and the grain milling industry reports a significant decline in the use of EDB for this use. There are also registered alternative fumigants available for stored grain fumigation. Alternatives for EDB fumigation of citrus and tropical fruits (such as irradiation and cold treatment) are being pursued, though they are not yet generally available on a commercial scale.

In conclusion, EPA believes that the appropriate long term solution for EDB is to eliminate public exposure by ending the pesticidal uses of the chemical, and regulatory actions were initiated in September 1983 to do that. The Agency is now gathering the information needed to assess current levels of public exposure and to determine what actions are appropriate to ensure that public health is protected during the time needed to eliminate the use of EDB and its residues from the food supply.

This concludes my statement, and I will be glad to answer any questions.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 6

OFFICE OF
EXTERNAL AFFAIRS

Honorable Dave Durenberger
Chairman
Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed are the Environmental Protection Agency's response to the questions you recently submitted to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances following the January 27, 1984 hearing before your Subcommittee.

I apologize for the delay in getting our responses to you. If I can be of further assistance, please feel free to contact me.

Sincerely yours,

Steadman M. Overman

Steadman M. Overman
Director
Office of Legislative Analysis

Enclosures

cc: Ron Outen

1. EPA was directed in 1972 to re-register all existing pesticides within three years, EDB is one example of one of those pesticides, and the Agency has been criticized for taking so long to reach a decision on EDB. To put this problem in perspective, please provide the following information:

   (a) Since 1972, how many pesticides have been reregistered, how many have had their registrations cancelled or substantially revised as a result of reregistration review, and how many are presently undergoing review?

   (b) How many pesticides are awaiting re-registration review, and how long will it take, at the present rate of activity, to complete the re-registration process on all of them?

EPA Response, part (a)

In 1972, amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provided for the reregistration of all previously registered pesticides (over 35,000 products) within three years. A system to accomplish this was developed in 1973; however, in 1975 when it became apparent that EPA was unable to accomplish the task, amendments to FIFRA specified that the Agency complete reregistration in the most expeditious manner possible. The system developed in 1973 called for categorizing products by chemical similarity of their active ingredients; all products in a group would then be reregistered at the same time. The system focused on identifying data gaps and calling in the needed data from registrants. It was based on the assumption that most data already on file with EPA were valid and properly reviewed and that any problems with the data had previously been identified.

However, during 1976 discussions with the Food and Drug Administration and the General Accounting Office, Senate hearings, and the Agency's own internal operations review raised serious questions about the adequacy of test data in EPA files and the completeness of the Agency's own review and follow-up. Consequently, implementation of the 1976 scheme was halted so the Agency could reexamine its assumptions and plans.

To deal with the massive data review problem, the Agency proposed to review data on a chemical-by-chemical basis. This generic approach, sanctioned by the 1978 amendments to the FIFRA, permits the Agency to make one comprehensive review and decision per pesticide chemical rather than multiple individual decisions for the many products containing the chemical. This scheme results in the development of a Registration Standard for a pesticide chemical which sets forth the conditions for reregistration of old products and registration of new products. EPA has identifed 578 active ingredients currently contained in registered pesticide products and thus subject to Registration Standard review. The Agency is using a cluster approach to Registration Standards development so chemicals with similar uses are reviewed at the same time. Clusters have been ranked so high volume and food use pesticides are given priority review, although some of the early standards were developed on small volume chemicals, selected primarily to develop and test the process.

The history, general philosophy, and procedures of the Registration Standards program are discussed in greater length in the attached copy of testimony presented to the Subcommittee on Agriculture, Research and General Legislation of the Senate Committee on Agriculture, Nutrition, and Forestry, on May 24, 1983, by Mr. Edwin L. Johnson, Director of the Office of Pesticide Programs.

By the end of FY 83, 65 Registration Standards had been issued. The 65 standards cover 2,378 high volume and food use products, or 6% of the total number of products registered by EPA. In terms of pesticide usage, this represents 34.5% of the total production of chemicals registered (approximately 2.7 billions pounds). By the end of FY 84, EPA will have issued a total of 90 Standards, which reflect review of chemicals representing about 43% of total pesticide usage in the United States. Future development plans call for completing 25 Registration Standards per year.

Of the products covered by the first 65 standards, 20% (approximately 475) were cancelled or suspended for failure to comply with the requirements of the Registration Standard. Over half of the reviews identified health and safety impacts which necessitated additional restrictions imposed through the Registration Standard. The majority of the restrictions are for precautionary labeling such as proper storage instructions; protective clothing requirements; reentry/preharvest intervals; and crop rotation restrictions.

To date, 70 Registration Standards have been completed. However, fewer chemicals have been reregistered, since the Agency considers a chemical re-registered only when registrants have satisfied the following requirements:

1. Compliance under FIFRA 3(c)(2)(B) with all data requirements listed in the Standard,
2. Submission of an acceptable label in accordance with the Registration Standard and current regulations,
3. Submission of a new Confidential Statement of Formula and submit or agree to submit all requested product chemistry data, and
4. Compliance with the data compensation provisions of FIFRA 3(c)(1)(D).

A court decision rendered in April 1983 by the U. S. District Court for the Eastern District of Missouri in the case of Monsanto v. EPA found portions of sections 3 (registration) and 10 (data release) of FIFRA unconstitutional. The Agency is currently appealing this decision to the Supreme Court where the case will be decided during the current Court session. However, in the meantime, the Court's decision prevents EPA from now requiring registrants to comply with provisions 2 and 4 cited above. Therefore, no reregistrations have been issued since April 1983. Prior to that date, approximately 70 products representing 4 active ingredients were reregistered.

In addition to the full Registration Standard review, the Agency has initiated a separate program to call in the long term chronic effects data on all registered chemicals. This program is progressing at a faster pace than the full Registration Standard review, and is designed to assure that at least the full chronic data base is available at the time the Registration Standard review begins. The Data Call-In program has called in the chronic data on 167 chemicals. The Data Call-In program has been successful in identifying inactive chemicals since, through suspensions or cancellations, 15 chemicals (or almost 10% of all active ingredients subject to the program) have come off the market.

EPA Responses, part (b)

By the end of FY 84, Registration Standards will have been completed for 90 chemicals, and 237 chemicals will have been covered by the Data Call-In program, out of the 578 total number of registered chemicals. The Registration Standard program is reviewing 25 chemicals per year so, assuming about 10% of the chemicals are cancelled or suspended, the program should be completed in the late 1990s. The Data Call-In program is calling in the chronic toxicity data on 70 chemicals per year, so it expects to complete the call-in of all 578 chemicals by 1989.

There are presently 1800 products awaiting reregistration. They are pending for various reasons including data waiver requests, ongoing label reviews, and EPA requests for additional information. For approximately 360 of the products awaiting reregistration, action is being delayed by requirements adopted as a result of the Monsanto court decision now pending before the Supreme Court.

2. Based on the information already published in Position Document 4, please submit a table setting forth the Agency's quantitative cancer risk estimates associated with:

(a) lifetime average dietary exposure to EDB;

EDB dietary exposures are discussed on pages 47 through 58 of the September 30, 1983, *EDB Position Document 4 (PD 4)* and the associated estimated cancer risks are discussed on pages 70 through 78. Exposures to contaminated grain were based on modelling results, because very little data existed on levels in grain-based consumer products. The levels for citrus residues were based on actual monitoring data of pulp levels for citrus shipped to California and treated in Florida. Actual residues in grain-based products appear to be 10 times less than the 34 parts per billion (ppb) estimated in the PD 4. These actual monitoring results are discussed in the February 8, 1984 Scientific Support Document concerning recent EPA grain contamination decisions on pages 10 to 30.

Levels of EDB in citrus being imported to the U.S. from Mexico and certain other countries are averaging 1,200 ppb in the edible pulp, considerably higher than the roughly 50 ppb used in the PD 4. However, it is important to note that imported citrus typically constitutes about 2% of the total fresh citrus available to U.S. consumers.

All papayas available to U.S. consumers have probably been treated with EDB, and about 80% of all mangoes have been treated. Generally levels of EDB are much lower in these commodities and are typically less than 50 ppb.

Cancer risks for these exposures can vary,from $1.7\text{x}10^{-5}$ to $2.8\text{x}10^{-4}$ depending on whether or not a state requires certain interstate shipments to be treated (page 72 of PD 4).

(b) EDB groundwater contamination (including a comparison to EDB levels actually found in contaminated wells);

Groundwater monitoring results, up to September 20, 1983, are discussed on pages 59 through 68 of the PD 4, and lifetime cancer risks are discussed on page 79. The levels typically range from limit of detection (0.02 ppb) to about 5 ppb; the respective lifetime cancer risks are $3x10^{-5}$ to $7x10^{-3}$. For a more complete discussion see the attached letter to Charles Clark, Director of Hawaii's Department of Health.

(c) occupational exposure to citrus workers;

These exposures and exposures to tropical fruit workers are discussed on pages 36 through 41 of the PD 4. Their associated lifetime cancer risks are discussed on pages 44 to 46 of the PD 4. As can be seen on page 46 the risks vary considerably depending on both exposure levels and duration of exposures; they can vary from $5x10^{-3}$ to 3 chances in 10 for a lifetime of exposure.

(d) occupational exposure to spot fumigation workers and grain mill workers.

Exposure to these groups of workers were not modified from the exposures estimated in the PD 2/3 which is attached to the PD 4. These exposures are discussed on pages 182 to 185. The lifetime cancer risks associated with these exposures are discussed on page 46. Again the risks vary depending on levels and duration from $6x10^{-3}$ to 1 chance in 10.

3. In your testimony, you state that the air pollution program has concluded that EDB in gasoline does not present a significant health risk compared to other gasoline components. Please provide the Subcommittee with the data and risk assessments that support this conclusion. These should include:

   (a) any unit risk estimates on EDB, benzene, and gasoline vapors performed by the Cancer Assessment Group or other entities;

   (b) information on emissions of these substances from tailpipes, fuel transfer, fugitive emissions and other vehicle-related sources;

   (c) for each of these substances, exposure estimates to gasoline refinery workers, transportation workers, gasoline station operators, consumers operating gasoline pumps, and the general public, and

   (d) any estimates of cancer incidence probabilities or the risk of other significant adverse health effects associated with gasoline that the Agency has in its possession.

The basis for the statement that EDB in gasoline does not present a more serious health risk than other gasoline components is based on our assessment that EDB emissions from gasoline are quite low and the associated risks are less than or similar to those posed by other gasoline emissions. In addition, EDB use in gasoline is steadily declining. These points are discussed in the attached memorandum of September 20, 1983, which includes an estimate of the relative risks posed by EDB in relation to other gasoline components.

Regarding the information provided on gasoline and its constituents, it should be emphasized that the Agency is now in the process of compiling an up-to-date assessment of the gasoline marketing industry which will include exposure and risk assessment for benzene, ethylene dibromide (EDB), ethylene dichloride (EDC) and gasoline vapor per se. This report will be publicly available in draft form in June or July 1984.

(a) The most recent unit risk estimates for benzene, unleaded gasoline vapor, EDB and ethylene dichloride (EDC) are provided in a December 21, 1983, memorandum from the Office of Health and Environmental Assessment. The memorandum also explains in detail the assumptions used to generate these numbers, which are upper limit estimates of lifetime (70 year) risk of cancer per unit of exposure. The unit risk numbers are:

1) **Benzene** 0.022 $(ppm)^{-1}$ or 6.9×10^{-6} $(ug/m^3)^{-1}$

2) **Unleaded Gasoline Vapor** 3.3×10^{-4} to 1.8×10^{-3} $(ppm)^{-1}$

3) **Ethylene Dichloride** 0.027 $(ppm)^{-1}$ or 6.6×10^{-6} $(ug/m^3)^{-1}$

4) **Ethylene Dibromide** 0.53 $(ppm)^{-1}$ or 6.8×10^{-5} $(ug/m^3)^{-1}$

(b) The principal source of information currently available on EDB emissions is a 1978 study by SRI International (copy enclosed). This report extrapolated many of its estimates of source specific emissions of EDB from a number of previous studies of benzene emissions. Vehicle emissions of EDB are described in Chapter VII of the SRI report and include the estimate that 24,000,000 people living in urban areas are exposed to annual average levels of EDB airborne concentrations between 1 and 5 parts per trillion. Ambient benzene levels in urban air are reported to be .01 to .05 parts per million.

(c) Estimates of benzene and EDB exposure resulting from pumping self-service gasoline are given in the SRI report (pp. 28-30). Estimates of ambient levels of EDB in the vicinity of gas stations is discussed on pages 30 through 36. Chapter V of the SRI report discusses petroleum refineries as a source of exposure for the general population, but not specifically for workers. Chapter VI discusses exposure in relation to gasoline storage and distribution. All of these estimates are geared to estimating ambient levels of EDB or benzene resulting from these stationary sources of emissions, and are not specific attempts to estimate exposure for workers.

(d) The health effects of EDB are discussed in EPA's position document already familiar to the Subcommittee. The health effects concerns about benzene are discussed in the enclosed report of the Carcinogen Assessment Group. The principal health concern for benzene is human leukemia.

4. Would you describe the primary chemical alternatives to EDB as a post-harvest fumigant? Please detail Agency data and previous and ongoing research regarding toxicity and food residues for these alternatives.

   (a) Specifically, what does the Agency know about hazards from methyl bromide, aluminum phosphide, and carbon tetrachloride? What data are available regarding residues on the foods to which these chemicals are applied? (Include carcinogenic studies and other studies in progress).

EPA's Response

A reasonably detailed list of the alternatives is described on pages 196 to 197 of the PD 4. A short discussion of the potential toxicity and regulatory status of some of the major alternatives appears in the attached paper entitled Current Status of the Grain Fumigants. There is also a brief discussion on pages 196 to 197 of the PD 4 and on pages 57 through 60 of the attached February 8 documents. Generally, there are either chronic or acute hazards which have been shown to result from exposures.

Both methyl bromide and aluminum phosphide pose acute toxicity hazards and can be life-threatening if improperly used. Methyl bromide has recently been reported to be oncogenic in a gavage (forced intubation) study in rats recently completed in the Netherlands. The Agency is currently reviewing this study. Methyl bromide is also a demonstrated mutagen in several cell systems. Methyl bromide is also being tested for oncogenicity via inhalation in the Netherlands. Similar studies in mice are being conducted under the direction of the National Toxicology Program. Carbon tetrachloride is a demonstrated carcinogen, causes cirrhosis of the liver, and other adverse effects and is currently undergoing an intensive risk/benefit review.

There is work underway with the Food and Drug Administration to obtain residue data on EDB's alternatives and the Agency is requiring certain other data to be submitted by the registrants through authority in Section 3(c)(2)(B) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

The following describes residue data currently available to EPA on methyl bromide, carbon tetrachloride and aluminum phosphide.

METHYL BROMIDE

Available data reflecting residue levels of methyl bromide, *per se*, in treated commodities are limited to blueberries, lentils, onions, pears, prickly pears, tea, various spices and yams. Residues immediately after treatment ranged as high as 150,000 ppb. With the exception of one sample of pears, which contained 40 ppb at 48 hours after treatment, no detectable residues were found in other commodities 24 hours after treatment.

The Agency has also received recent residue data from California on citrus fumigated in Florida. These data show that residues in the pulp vary from 2 ppb to 170 ppb and in whole fruit they vary from 2 ppb to 130 ppb.

The receipt of additional residue data is essential to accurate assessment of dietary risk, if any, from consumption of foods fumigated with methyl bromide.

CARBON TETRACHLORIDE

Most of the available residue data for carbon tetrachloride are contained in the 1967 Evaluations of Some Pesticide Residues in Food FAO/WHO, Rome 1968; 1971 Evaluations of Some Pesticide Residues in Food, WHO, Geneva, 1972; and Pesticide Residues in Food-1979, Evaluations FAO, Rome, 1980. EPA has exempted carbon tetrachloride from the requirement for a tolerance on grains.

Carbon tetrachloride is used as a fumigant by itself, but it is more commonly mixed with other fumigants including carbon disulfide and methyl bromide. It should be noted that carbon tetrachloride is not uniformly distributed through the commodity when applied to the surface. After a few days the lower parts of the bulk contain the higher residue amount. The rate of dissipation of carbon tetrachloride depends on the temperature, moisture content of the grain and air-tightness of the storage containers.

When carbon tetrachloride was applied to raw cereal grains at normal commercial dosages, residues shortly after treatment ranged from 100-200 parts per million (ppm). After storage, without specifically airing the grain, residues fell to about 50 ppm within a few months. Flour milled from grain with residue levels of 20-60 ppm carbon tetrachloride contained 2-10 ppm. Residues in bread made from the flour were below 0.005 ppm. Other studies showed similar residue levels in grain. The highest residue level found in bread containing flour milled from carbon tetrachloride treated grain was 0.13 ppm.

ALUMINIUM PHOSPHIDE

Aluminum phosphide reacts rapidly with moist air to form a volatile phosphine gas. Residue studies on aluminum phosphide consistently show that resulting residues of phosphine in grain are low ranging from 0-0.03 ppm 1-14 days after treatment and 0.0006-0.012 ppm after turning and aerating.

The persistence of residues of phosphine in baked bread has also been assessed in a study where flour fortified with 13.4 ppm of phosphine was baked into bread. The bread showed an apparent phosphine residue of 0.03 ppm. Thus, when flour was treated at an exaggerated level immediately before baking, residues remained well below the established tolerance level.

5. How widely used is methyl bromide in this country, and how much does EPA know about this chemical?

EPA's Response

In response to the first part of this question, I have attached a copy of a Preliminary Quantitative Usage Analysis of methyl bromide which sets forth the pounds used in 1978-1979 on both agricultural and industrial/chemical sites.

The response to question 4 responds to the second portion of this question concerning what EPA knows about methyl bromide.

6. Please provide data in the Agency's possession concerning EDB levels in domestic and imported citrus and other fruits and vegetables. Is it the Agency's opinion that we should be more concerned about exposure through citrus than through grain products, or vice versa?

   (a) Is there a greater problem from an average amount of citrus in one's diet compared with average grain intake? Which is the greater danger?

   (b) What regions of the country have the most EDB residues on citrus?

   In addition to the data already discussed in question 2a, the Agency has received recent reports from FDA and the State of California (see letters dated February 8 and 27, 1984, from FDA to EPA and letter dated February 7, 1984 to EPA from California Department of Food and Agriculture).

EPA's Response

(a) No, there is not a greater problem through EDB residues in citrus and tropical fruits than compared to grains. Although the levels in citrus and tropical fruits are considerably higher, consumers eat much less fresh citrus and much less contaminated citrus than they eat contaminated grain-based products. Futhermore, grain-based products are a much larger portion of the average consumer's diet. Copies of the technical support documents prepared for the emergency suspension of EDB as a grain fumigant (February 8, 1984) and the tolerance setting on citrus (March 2, 1984) are enclosed. The documents provide greater detail.

(b) Until three weeks ago, California residents consumed a much larger percentage of treated citrus than other parts of the country. Arizona and New Mexico residents probably experienced somewhat similar exposures. These states required that citrus originating in Florida or Mexico be treated with EDB prior to export. However, Florida has recently switched to using methyl bromide treatment and the borders were very recently closed to shipments from Mexico because of a disease occuring on Mexican oranges.

December 21, 1983

SUBJECT: Issues Concerning Unit Risk Estimates Relevant to Gasoline Marketing

FROM: Elizabeth L. Anderson /s/
Director
Office of Health and Environmental Assessment (RD-689)

TO: David Patrick
Chief
Pollutant Assessment Branch (MD-12)

In response to your December 6, 1983 memorandum and our subsequent December 8, 1983 meeting we hope the following comments will clarify the issues you raised concerning unit risk estimates we have made for benzene, unleaded gasoline, ethylene dibromide and ethylene dichloride.

The upper limit unit risk estimates we have generated are:

1) Benzene 0.022 $(\mathrm{ppm})^{-1}$ or 6.9×10^{-6} $(\mathrm{ug/m^3})^{-1}$

2) Unleaded Gasoline Vapor 3.3×10^{-4} to 1.8×10^{-3} $(\mathrm{ppm})^{-1}$

3) Ethylene Dichloride 0.027 $(\mathrm{ppm})^{-1}$ or 6.6×10^{-6} $(\mathrm{ug/m^3})^{-1}$

4) Ethylene Dibromide 0.53 $(\mathrm{ppm})^{-1}$ or 6.8×10^{-5} $(\mathrm{ug/m^3})^{-1}$

I. Credibility of Risk Estimates

As with all unit risk estimates, these values were derived with several standard assumptions in the absence of information to the contrary. The major assumptions are:

1) The agent really is a human carcinogen.

2) The linear dose-response relationship expresses a plausible upper bound of risk at the small doses typically occurring in the environment.

3) In the absence of human data on carcinogenicity

   a) Animal bioassays are appropriate for human risk estimation.

   b) Humans are as sensitive as the most sensitive animal species.

   c) If the route of adminstration is not appropriate to the human exposure situation, equal fractional uptakes are assumed via the two routes.

For each of the agents, these general assumptions are discussed below:

1. Benzene

Strong evidence of human carcinogenicity exists for benzene in three human studies of highly exposed workers. According to reports by three separate groups, it is carcinogenic in both rats and mice and by both gavage and inhalation routes of exposure. This evidence would place benzene in IARC category 1, which are known human carcinogens. Therefore, assumption 1 is well-founded and the qualitative evidence of carcinogenicity is better for benzene than for the other three agents.

The unit risk estimate was based on the average of the three human studies, assuming a linear dose response function. Therefore assumption 3 is not necessary. However the unit risk estimated from the three animal studies using this model is very close to this value, so that there is an unusual degree of consistency between human and animal estimates of unit risk. The major justification for linearity at low dose (assumption 2), namely the theory that cancers are initiated by mutations which follow a linear non-threshold dose response curve, is incomplete for benzene, since it is known not to be mutagenic. Therefore the plausibiltiy of the upper bound is not as certain as the mutagenic agents.

2) Unleaded Gasoline

The evidence of carcinogenicity for unleaded gasoline consists of positive responses via inhalation in both rat kidney and mouse liver. The human evidence for carcingenicity is inadequate. This combined evidence would place unleaded gasoline in the IARC category 2b, which are probably carcinogenic in humans. Therefore assumption 1 is less certain than for benzene.

The unit risk estimate based on a linear non-threshold dose extrapolation is given as a range between two limits rather than as a single value. The upper end of the range is derived from the mice data and lower end from the rat data. Normally we would use the mice data because it yields the more sensitive unit risk estimate (assumption 3b), but for unleaded gasoline there is fragmentary evidence of human kidney cancer associated with exposure to gasline. The rat kidney response, giving the lower risk estimate, would be more appropriate if the human information were confirmed. However, we have no way of knowing which end of the range is more appropriate. Unleaded gasoline has not been found to be mutagenic, although it has not been as well tested as benzene. Therefore the plausibility of the upper bound is not as certain as it is for the mutagenic agents.

3. Etyhylene Dichloride (EDC)

No human evidence of carcinogenicity is available. The animal evidence consists of positive responses at several sites in male rats and mice via gavage. This evidence would place it in IARC category 2b, which are probably carcinogenic in humans. Therefore, assumption (1) is less plausible than for benzene.

The unit risk for EDC inhalation was similar by two separate methods of estimating inhalation risks from gavage data, but the absence of direct inhalation data in animals makes the unit risk estimate less firmly-based than estimates for the other three agents because assumption 3c must be used. The linear dose response relationship is plausible for EDC because there is multi-test evidence of mutagenicity.

4) Ethylene Dibromide (EDB)

No human evidence of carcinogenicity is available. The animal evidence consists of positive responses in mice in both inhalation and gavage bioassays and nasal cavity tumors in rats following inhalation exposure. This evidence would place EDB in IARC category 2b which are probably carcinogenic in humans.

The unit risk was obtained from the rat inhalation experiment using the linear dose-response extrapolation procedure. Since there is good evidence of mutagenicity for EDB, the plausibility of the estimate is higher than for the non-mutagenic agents. Therefore, assumption 2 is valid for EDB. Since there is only one animal inhalation test, assumptions 3b and 3c do not have to be used.

The estimate used by the Office of Toxic Sustances was based on the gavage experiment and was meant to be used with ingested EDB rather than inhaled EDB. Therefore, the differences in the two estimates should be of no particular concern.

In summary, the credibility of the unit risk number depends on two different types of evidence: 1) the weight-of-evidence that the agent is a human carcinogen and 2) the soundness of the quantitative unit risk estimate. The latter factor itself has two aspects: a) the plausibility that the linear non-threshold model represents an upper limit on the risk and b) the firmness of the calculation, considering the nature of the data sources and assumptions that must be made in the calculation.

The ranking of the four agents on the weight-of-evidence scale clearly puts benzene first and the other three lower down and not appreciably different from each other. With respect to the soundness of the quantitative estimates, the modeling aspect would put EDB and EDC higher than benzene and unleaded gasoline, where as the firmness of calculation would put benzene highest because of consistency between the various studies, EDC the lowest because of inappropriate route of exposure in the animal studies and EDB and unleaded gasoline in the middle. The following table summarizes these judgements and presents rankings of the four agents under two assumptions: a) equal weight for the two factors and b) assuming that the plausibility of the linear model is more important than the firmness of the calculation.

			Ranking, assuming that:	
	Plausibility of Linear Model	Firmness of Calculation	Equal Weights	Plausibility weighted higher than firmness
Benzene	Lower	High	2	3
Unleaded gasoline	Lower	Medium	4	4
EDC	Higher	Low	2	2
EDB	Higher	Medium	1	1

This summary of quantitative factors shows that EDB and EDC rank highest and unleaded gasoline ranks the lowest in credibility. This can not be very adequately combined with the qualitative weight-of-evidence because the most well established carcinogen (benzene) has a relatively insecure unit risk number. Unleaded gasoline, which like EDC and EDB is not a known human carcinogen, tends to rank low in the quantitative factors as well.

II. External Review of the Unit Risk Factors

A) Benzene - No plans are being made to further review the unit risk factor, since it has received extensive review and confirmation by at least 5 independent groups.

B) Unleaded Gasoline - The qualitative report has been peer reviewed but the unit risk calculation itself has not undergone review. We see no need for a review since the methodology for these calculations has been reviewed and approved.

c) Ethylene Dichloride - This will undergo thorough review during the process of SAB approval of the EDC health document.

d) Ethylene Dibromide - The oral risk estimate that CAG prepared for the Office of Pesticides Program (OPP) was reviewed by the public and the Science Advisory Panel. The inhalation estimate will be reviewed in conjunction with future actions of OPP.

III. Volatilization Versus Extrapolation of Gasoline Vapor

The gasoline vapor to which people are exposed in the environment consists primarily of the most volatile components of the mixture, whereas in the animal experiments the entire mixture was aerosolized and inhaled. Since the identity of the carcinogenic components is not known, we have no way of knowing whether the potency of the vapor is equal to, more than or less than that of the complete mixture. However, regardless of this uncertainty humans are exposed to the same material as the animals, so the animal results are relevant in some degree to the human exposure situation.

The remaining issues in your memorandum have been discussed above.

cc: B. Goldstein (RD-672)
S. Baker (RD-672)
P. Jutro (RD-672)
D. Clay (TS-792)
E. Johnson (TS-766)
D. Taylor (OAQPS-RTP)

Preliminary Quantitative Usage Analysis
of

Methyl Bromide

Economic Analysis Branch
Benefits and Field Studies Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

March 1980

Table 1

Derivation of Net Supply for Domestic Usage of Methyl Bromide as a Pesticide, Typical Current Year Basis (1978-79).

	Pounds Active Ingredient (000)
Domestic Production	60,000-80,000
Imports	NA
Exports	35,000-45,000
Net Supply for Usage	25,000-35,000

NA means not immediately available.

Table 2

Domestic Usage of Methyl Bromide as a Pesticide
by Usage Sector and Site, Typical Current Year Basis (78-79.

Sectors/Site	Approx. Quantity A. I. Pounds(000)	 Percent	Pct. of Site Treated Per Yr.	Regional/States Usage Info. 1/	Commodity Imports with Residues 2/
Agricultural:					
Major sites					
tobacco	6,700	30.2	80-90	South/Eastern U.S.	
tree fruits nuts/nurseries	4,860	21.9	NA	CA,FL	
tomatoes	2,070	9.3	60-70	CA,FL	
misc	100	0.5	NA	NA	
Total	13,730	61.8			
Industrial/Commercial:					
Major sites					
commodity/space	4,340	19.5	5-10	Mid/West	
structural-pest control	1,050	4.7	NA	South	
greenhouse/turf ornamentals-floral/crops	2,580	11.6	NA	NA	
misc	520	2.3	NA	NA	
Grand Total	22,220	100.0			

1/ For example, mention principal usage areas (or where commodity is grown); probable regional/state concentrations; even distribution across entire site, etc.

2/ Mention likely exporting nations of commodity which could have residue if known.

Note: NA means data not immediately available.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 27 1984

Mr. Edwin L. Johnson
Director
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Ed:

Enclosed are the results from FDA's survey of imported tropical fruits for residues of ethylene dibromide. These results have been given previously by phone to Dr. Richard Schmidt of your Residue Chemistry Branch. Although this survey is completed there may be a few more results which we will provide to you at a later date.

If you have any questions regarding the enclosed data, please let me know.

Sincerely yours,

John R. Wessel

Enclosure

Ethylene Dibromide (EDB) in Tropical Fruit*

Results to Date 2/24/84

Analyzing District	Product	Country of Origin	Parts per billion (ppb) EDB		
			Whole	Peel	Pulp
MIN-DO	Papaya	Hawaii	170	9.9	26.6
"	"	"	72.9	1.3	2.7
"	Mango	Haiti	32.2	3.6	2.8
"	Papaya	Hawaii	304	6.7	14.3
"	Mango	Haiti	2.0	1.2	Trace
"	Banana	Costa Rica	none	-	-
"	Pineapple	Hawaii	"	-	-
"	"	"	"	-	-
"	"	"	"	-	-
LOS-DO	Mango	Haiti	"	-	-
"	"	"	2	-	-
"	Papaya	Hawaii	280	24	47
"	"	"	80	1	3
"	"	"	80	2	4
"	"	"	180	24	24
"	"	Mexico	1	-	-
"	Pineapple	Hawaii	none	-	-
NOL-DO	Banana	Honduras	none	-	-
"	"	"	"	-	-
"	"	"	"	-	-
NYI-DO	"	"	"	-	-
"	"	"	"	-	-
"	"	Columbia	"	-	-
"	"	"	"	-	-
"	"	Ecuador	"	-	-
"	"	Costa Rica	"	-	-
"	"	Columbia	"	-	-
"	Pineapple	Honduras	"	-	-
"	Papaya**	Brazil	238	26.1	157
"	Mango**	Dom. Rep.	2,880	1,410	833
BUF-DO	Banana	Columbia	none	-	-
LOS-DO	Pineapple	Hawaii	none	-	-
SAN-DO	Mango	Haiti	3.8	-	-
"	Cucumber	Hawaii	1.8	-	-
SJN-DO	Mango	Puerto Rico	none	-	-
"	"	Dom. Rep.	"	-	-
"	Papaya	"	"	-	-
"	"	Puerto Rico	"	-	-
"	"	"	"	-	-
"	"	"	"	-	-

* Samples collected a wholesale level, except where marked with *** which were collected at port of entry.

* Fumigated in U.S.

Ethylene Dibromide (EDB) in Tropical Fruit
(continued)

Analyzing District	Product	Country of Origin	Parts per billion (ppb) EDB		
			Whole	Peel	Pulp
SJN-DO	Papaya	Puerto Rico	none	-	-
"	"	"	"	-	-
"	Frozen (guava) Guanabana	Dom. Rep.	"	-	-
"	Banana	Undetermined (Puerto Rico)	"	-	-
"	Mango	"	"	-	-
"	"	"	"	-	-
"	Papaya	"	"	-	-
MIN-DO	Banana	Costa Rica	"	-	-
"	Plantain	Ecuador	"	-	-
"	"	Costa Rica	"	-	-
"	Banana	Honduras	"	-	-
"	"	Columbia	"	-	-
"	Pineapple	Hawaii	"	-	-
"	Ugli Fruit	Jamaica	6.0	4.9	Trace
SJN-DO	Honey Dew Melon	Puerto Rico	none	-	-
"	Cantaloupe	"	"	-	-
"	Mango	"	"	-	-
DAL-DO***	Banana	Mexico	"	-	-
"	"	"	"	-	-
"	Pineapple	"	1.2	-	-
"	Mango	"	747	133	78
"	"	"	1009	362	109
SJN-DO	Pineapple	Santo Domingo	none	-	-
"	"	Puerto Rico	"	-	-
"	"	"	"	-	-
"	Guanabana (guava)	"	"	-	-
"	Corazon	"	"	-	-
"	Plantain	Santo Domingo	"	-	-
"	Banana	"	"	-	-
"	Cantaloupe	"	"	-	-
BUF-DO	Raisins	Turkey	none	-	-
"	"	"	"	-	-

Summary

No. Samples	Product	Positives
16	Papaya	9
13	Mango	7
18	Banana	0
11	Pineapple	1
4	Plantain	0
1	Cucumber	1
2	Guava	0
1	Ugli Fruit	1
1	Honey Dew	0
2	Cantaloupe	0
1	Corazon	0
2	Raisins	0
72		19

STATE OF CALIFORNIA GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF FOOD AND AGRICULTURE

1220 N Street
Sacramento
95814

February 7, 1984

Dr. Jack Moore, Assistant Administrator
Office of Regulatory Reform
Pesticides and Toxic Substances
Environmental Protection Agency
401 M Street, S.W. TS 788
Washington, D.C. 20460

Dear Dr. Moore

Enclosed are the results of fruit analyses for EDB conducted by our Department between 1980 and 1984.

Clare and I enjoyed meeting with you in St. Louis and look forward to a close working relationship.

Sincerely

Lori Johnston

Lori Johnston, Assistant Director
Division of Pest Management, Environmental
Protection and Worker Safety
(916) 322-6315

Enclosures

FEB 9 198

Office of the Assistant [illegible]
For Pesticides and Toxic [illegible]

CITRUS E.D.B. ANALYSIS

1984

DATE	INSPECTOR NUMBER	DISTRICT	FRUIT	LOCATION	ANALYSIS IN PPB		
					PULP	PEEL	Total
4/84	AC-1-R-7	Downey	Grapefruit	Florida	250	4500	est 4000
5/84	GR-1584-1	Berkeley	Grapefruit	Florida	350	1440	
5/84	GB-1584-2	Berkeley	Grapefruit	Florida	200	1560	
5/84	DA-84-1	Berkeley	Grapefruit	Florida	60	670	
5/84	BC-262	Sacramento	Grapefruit	Florida	380	12,500	
5/84	BG-263	Sacramneto	Grapefruit	Florida	17	2	
5/84	KAC-533	Sacramento	Tangello	Florida	300	3,260	
5/84	GF-100	Berkeley	Lime	Florida	0	0	
6/84	JM-2419-R	Downey	Orange	Mexico	1420	7,620	4080
6/84	*BG-265	Sacramento	Grapefruit	Florida	2	5	4
6/84	*BG-264	Sacramento	Grapefruit	Florida	1	12	10
9/84	JM-2413-W	Downey	Grapefruit	Florida	175	4500	1280
9/84	CA-1357	Berkeley	Grapefruit	Florida	55	970	380
9/84	CA-1356	Berkeley	Grapefruit	Florida	35	5200	1400
9/84	JF-0001	Berkeley	Grapefruit	Florida	7	2	5
9/84	JF-0002	Berkeley	Grapefruit	Florida	0	0	0
9/84	JM-2416-W	Downey	Grapefruit	Florida	11	4720	2120
9/84	JM-2415-W	Downey	Grapefruit	Florida	74	3070	260
9/84	JM-2418-R	Downey	Grapefruit	Florida	36	3240	1100
9/84	JM-2417-W	Downey	Grapefruit	Texas	0	13	4
9/84	JM-2414-R	Downey	Grapefruit	Texas	16	1530	470
5/84	KAC-534	Sacramento	Tangello	Florida	61	85	
12/84	OR-102-D	Downey	Orange	Mexico	420	380	1710
12/84	JW-910	Downey	Orange	Mexico	580	3740	1670
12/84	JB-1-84-25	Berkeley	Lime	Mexico	7	110	70
12/84	JM-2400-W	Downey	Orange	Mexico	540	8680	3500
12/84	JW-909	Downey	Orange	Mexico	340	16500	3820

* Samples drawn from retail grocery store.

SAMPLES TESTED FOR E.D.B

DATE	INSPECTOR NUMBER	FRUIT	LOCATION	ANALYSIS IN PPB	
				PULP	TOTAL
1/26/84	ENS1052	Papayas	Hawaii	2.0	
1/26/84	ENS1053	Papayas	Hawaii	1.0	
1/26/84	ENS1054	Papayas	Hawaii	2.0	
(New Shipment) →	ENS1056	Papayas	Hawaii	14.0	
1/27/84	CA1365	Papayas	Hawaii	11.0	
	CA1364	Papayas	Hawaii	3.1	
	GF101	Papayas	Hawaii	4.8	
	DA8433	Papayas	Hawaii	11.3	
	DA8432	Papayas	Hawaii	12.0	
(New Shipment) ↘ 1/30/84	OR225W	Papayas	Hawaii	24.7	
	OR231W	Papayas	Hawaii	13.0	
1/26/84	ENS1055	Mango	Hati	2.0 Pulp Only	
1/27/84	CA1366	Mango	Brasil	1.0 Pulp & Peel	

EDB ANALYSIS - 1983

LAB NO.	COMMODITY	LOCATION	ANALYSIS IN PPB		
			PULP	SEED: Heart	Shell
68	Mango	Unknown	ND	15	ND *
1548	Papaya (Seed)	Hawaii	TOTAL: 35		
2490	Carrots	Unknown	TOTAL: ND		
2491	"	"	TOTAL: ND		
2492	"	"	Washed: .3	Unwashed: 1.1	
2493	"	"	Washed: 1.3	Unwashed: 5.7	
			Soil from carrots: 33.2		
2494	"	"	Washed: ND		
2495	"	"	" ND		
2496	"	"	" ND		
2497	"	"	" ND		
2498	"	"	" ND		
2499	"	"	" ND		
2500	"	"	" ND		
2501	"	"	" ND		
2502	"	"	" ND		
2503	"	"	" ND		
2574	"	"	" ND		
2575	"	"	" ND		
2576	"	"	" ND		
2577	"	"	" ND		
2578	"	"	" ND		
2579	"	"	" ND		
2580	"	"	" ND		
2581	"	"	" ND		
2582	"	"	" ND		
2583	"	"	" ND		
2584	"	"	" ND		
2585	"	"	" ND		
3440	Papaya (Seed)	"	SEED: 2000		

* ND = None Detected

EDB ANALYSIS - 1982

LAB NO.	COMMODITY	LOCATION	ANALYSIS IN PPB		
			PULP	PEEL	TOTAL
1	Oranges	Fumigation Study	397	3640	1500
2	"	" "	95	1320	598
9	"	" "	8	101	80
13	Grapefruit	" "	530	16,560	6470
14	"	" "	575	16,620	6420
40	"	" "	1130	27,000	10,790
41	"	" "	1280	27,540	10,690
42	"	" "	1050	23,180	7460
43	"	" "	1300	26,200	10,100
44	Oranges	" "	3130	68,700	25,020
52	Grapefruit	" "	1670	17,380	8320
53	"	" "	1460	14,040	6500
54	Oranges	" "	940	4930	2210
55	Grapefruit	" "	320	4430	2130
56	Oranges	" "	2600	29,020	11,750
57	Lemons	" "	2120	29,160	15,230
58	"	" "	1310	41,920	17,570
59	Oranges	" "	2870	30,970	10,870
60	Grapefruit	" "	1120	21,860	8150
61	"	" "	810	17,600	5960
62	"	" "	870	17,540	7110
63	Oranges	" "	3130	34,180	10,800
64	Grapefruit	Unknown	240	1440	570
65	"	"	190	780	420
66	"	"	150	450	230
67	"	"	320	1780	820
68	"	Fumigation Study	1420	30,480	10,940
69	Lemons	" "	1160	29,470	10,690
70	Oranges	" "	1160	11,730	4560
71	Grapefruit	" "	530	15,850	5820
72	Lemons	" "	1500	25,690	11,640
73	Lemons	" "	1040	12,120	8890
74	Grapefruit	" "	1230	17,900	9870
75	Oranges	" "	3960	44,390	17,060
76	"	" "	1390	10,160	4430
77	Lemons	" "	1620	48,890	19,980
78	Grapefruit	" "	1140	28,960	10,970
79	Oranges	" "	2310	37,620	12,390
80	Lemons	" "	740	47,920	18,790
81	Oranges	" "	1370	14,340	5770
82	Lemons	" "	92	21,010	8540
83	"	" "	1660	51,860	21,900
84	Oranges	" "	2000	20,080	8390
85	Grapefruit	Texas	280	3710	1100
90	Lemons	Fumigation Study	929	2077	1430
91	Grapefruit	Texas	210	1560	670
92	"	Fumigation Study	1190	9660	4380
93	"	" "	1630	52,800	18,630
94	"	" "	ND	ND	ND *

* ND = None Detected

EDB ANALYSIS - 1982

			ANALYSIS IN PPB		
LAB NO.	COMMODITY	LOCATION	PULP	PEEL	TOTAL
95	Oranges	Fumigation Study	3250	38,100	17,020
96	Grapefruit	" "	810	11,940	4470
97	"	" "	650	14,270	5730
98	Lemons	" "	750	17,980	7440
99	Grapefruit	" "	350	8380	4300
100	"	" "	410	6860	4210
101	Oranges	" "	1760	13,150	7360
102	Lemons	" "	450	10,660	6050
104	Grapefruit	" "	190	2650	1570
105	"	" "	198	1720	1400
106	"	" "	5120	5320	
107	"	" "	539	6260	2710
108	"	" "	444	4250	2040
109	"	" "	247	5830	2250
113	"	" "	618	12,770	6110
114	"	" "	264	2990	1200
115	"	" "	1260	18,520	8050
116	"	" "	300	23,770	11,360
117	Lemons	Unknown	500	880	610
120	Oranges	"	ND	4	ND *
121	"	"	ND	7	ND
122	"	"	ND	ND	ND
123	"	"	ND	7	ND
124	Lemons	Fumigation Study			49,570
125	"	" "			51,740
126	"	" "			43,480
127	"	" "			47,520
128	"	" "			42,080
129	"	" "			41,580
130	"	" "			53,540
131	"	" "			45,670
132	"	" "			49,580
133	"	" "			38,370
134	"	" "			39,340
135	"	" "			33,880
136	"	" "			46,330
137	"	" "			41,500
138	"	" "			38,130
139	"	" "			46,080
140	"	" "			29,830
141	"	" "			31,510
142	"	" "			28,700
143	"	" "			47,350
144	"	" "			26,410
145	"	" "			17,860
146	"	" "			21,150
147	"	" "			18,780
148	"	" "			16,340
149	"	" "			24,760
150	"	" "			19,080

* ND = None Detected

EDB ANALYSIS - 1982

LAB NO.	COMMODITY	LOCATION	ANALYSIS IN PPB PULP	PEEL	TOTAL
151	Lemons	Fumigation Study			16,000
152	"	" "			15,250
153	"	" "			17,940
154	"	" "			15,360
155	"	" "			12,020
156	"	" "			14,940
157	"	" "			14,470
158	"	" "			8613
159	"	" "			7740
160	"	" "			9740
161	"	" "			10,360
165	Oranges	" "	760	6630	3570
166	Grapefruit	" "	500	9820	4470
167	"	" "	800	9100	3820
168	"	" "	366	4020	1780
169	"	Unknown	68	92	125
169A	"	"	270	2780	1280
170	"	"	90	379	201
170A	"	"	255	1920	709
171	"	"	6	68	46
171A	"	"	38	319	106
172	"	"		None recorded	
173	"	Fumigation Study	110	1200	652
174	Oranges	" "	441	3940	1540
185	"	" "	78	150	88
190	Grapefruit	Unknown	23	43	33
193	"	"	30	11	47
200	Lemons	Fumigation Study	1660	98,830	42,860
201	"	" "	2680	138,890	49,000
203	"	" "	3400	103,990	39,670
205	"	" "	3440	86,310	39,830
207	"	" "	2330	75,400	29,300
210	"	" "	2450	69,850	28,280
211	"	" "	2610	63,590	27,870
213	"	" "	2050	64,540	27,610
215	Grapefruit	" "	39	111	48
216	"	" "	18	58	29
243	Lemons	" "			24,810
244	"	" "			18,080
245	"	" "			15,180
246	"	" "			16,620
247	"	" "			16,120
248	"	" "			13,420
249	"	" "			12,990

EDB ANALYSIS - 1982

			ANALYSIS IN PPB		
LAB NO.	COMMODITY	LOCATION	PULP	PEEL	TOTAL
327	Oranges	Fumigation Study	950	29,530	12,920
328	"	" "	998	43,920	16,640
329	Grapefruit	" "	2780	20,090	8680
330	Oranges	" "	644	19,480	8610
331	"	" "	827	28,760	9200
332	"	" "	200	5420	1830
333	"	" "	530	13,320	4900
334	"	" "	580	17,350	7780
335	"	" "	650	25,900	8140
336	"	" "	410	12,460	3700
513	Mangos	Unknown	12.2		

EDB ANALYSIS - 1981

LAB NO.	COMMODITY	LOCATION	ANALYSIS IN PPB FRUIT	SEED	
1486	Cherries	Fumigation Study	16,200	156,000	
1487	"	" "	3960	69,400	
1488	"	" "	ND	ND	*
			PULP	PEEL	TOTAL
2832	Limes	Texas	ND	4	
2833	Grapefruit	"	190	1920	
2834	"	"	ND	12	
2835	"	"	9	82	
2836	"	"	510	3440	
2839	"	"			75
3243	Oranges	Fumigation Study	350	1340	910
3275	Lemons	" "	867	11,530	7160
3276	"	" "	266	2460	5570
3278	Citrus	" "	3190	125,220	59,660
3279	"	" "	4570	132,650	62,920
3280	"	" "	6830	137,560	60,100
3288	Oranges	" "	15	61	22
3289	"	" "	377	6490	1940
3298	"	" "	ND	8	ND
3299	"	" "	33	110	52
3300	"	" "	26	113	61
3301	"	" "	1240	33,790	12,020
3302	"	" "	1320	67,660	27,400
3322	"	" "	6	5	4
3323	"	" "	ND	ND	ND
3324	"	" "	ND	ND	17
3325	"	" "	6	15	11
3326	"	" "	1730	43,400	14,360
3327	"	" "	22	72	41
3328	"	" "	2790	48,340	18,380
3329	"	" "	2060	31,770	13,490
3330	"	" "	26	28	24
3331	"	" "	1970	27,080	10,490
3332	"	" "	2310	29,290	11,920
3339	"	" "	1090	20,940	8570
3340	"	" "	4530	104,320	38,100
3341	"	" "	2800	90,910	30,890
3342	"	" "	5670	116,250	42,740
3343	"	" "	4620	109,010	45,430
3344	"	" "	3000	80,690	34,210
3345	"	" "	4070	74,570	31,170
3346	"	" "	3550	64,240	26,250
3347	"	" "	3570	70,280	26,490
3376	"	" "	2650	38,110	14,970
3377	"	" "	1800	23,790	49,180
3385	"	" "	544	13,900	5710

* ND = None Detected

EDB ANALYSIS - 1980

LAB NO.	COMMODITY	LOCATION	ANALYSIS IN PPB PULP	PEEL	TOTAL
56	Grapefruit	Florida	-	-	1370
59	Grapefruit	Florida	-	-	1150
62	Grapefruit	Florida	-	-	3
65	Grapefruit	Florida	-	-	260
68	Limes	Florida	-	-	7
71	Grapefruit	Florida	-	-	2510
74	Grapefruit	Florida	-	-	270
77	Grapefruit	Florida	-	-	1080
80	Grapefruit	Florida	-	-	2220
83	Grapefruit	Florida	-	-	2740
86	Grapefruit	Florida	-	-	4
89	Grapefruit	Texas	-	-	140
92	Oranges	Florida	-	-	970
95	Oranges	Texas	-	-	2260
106,107,108	Oranges	Texas	130	660	250
115,116,117	Oranges	Texas	520	9650	3340
124,125,126	Oranges	Unknown	70	480	180
133,134,135	Oranges	Texas	90	2130	450
142,143,144	Tangerines	Florida	320	11,410	2730
151,152,153	Oranges	Texas	220	2080	480
160,161,162	Oranges	Texas	360	6960	2690
169,170,171	Oranges	Unknown	30	30	30
202	Oranges	Unknown			ND *
203	Oranges	Unknown			ND
204	Oranges	Unknown			ND
205	Oranges	Unknown			ND
206	Oranges	Unknown			ND
207	Oranges	Unknown			ND
208	Oranges	Unknown			ND
209	Oranges	Unknown			ND
210	Oranges	Unknown			ND
226	Oranges	Unknown			ND
227	Oranges	Unknown			ND
228	Oranges	Unknown			ND
229	Oranges	Unknown			ND
230	Oranges	Unknown			ND
231	Oranges	Unknown			ND
528	Oranges	Unknown			ND
529	Oranges	Unknown			ND
530	Oranges	Unknown			ND
531	Oranges	Unknown			ND
532	Oranges	Unknown			ND
533	Oranges	Unknown			ND

* ND = None Detected

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

February 8, 1984

Mr. Edwin L. Johnson
Director
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Ed:

Enclosed are the final results from FDA's completed survey of imported and domestic citrus and citrus products for residues of ethylene dibromide.

As you can see, no residues of EDB were detected in any of the 48 samples of imported and domestic citrus juices and other products. Of the 82 samples of domestic citrus, only 8 were positive for EDB with levels ranging from 1.2 to 1,515 parts per billion (ppb) in the whole fruit and less than 1 to 338 ppb in the edible fruit. In imported citrus samples, however, only 8 out of 49 samples were negative for EDB residues. Of the positives, levels ranged from less than 1 to 16,100 ppb in the whole fruit, 4 to 45,263 ppb in the peel, and 1.3 to 6,250 ppb in the edible pulp.

For your additional information, we are in the process of analyzing a few of the citrus samples with high EDB levels to determine the level of inorganic bromide residues. We will also provide these results to you when the analyses are completed.

If you have any questions regarding the enclosed data, please let me know.

Sincerely yours,

Catherine W Carnevale

John R. Wessel
Scientific Coordinator
Office of Regulatory Affairs

Enclosures

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FEB 9 1984
OFFICE, DIRECTOR OF PESTICIDE [illegible]

TABLE 1

Ethylene Dibromide (EDB) in Imported Citrus Fruits

Analyzing District	Collect. Location	Sample Number	Product	Parts per billion (ppb) EDB Whole	Peel	Pulp	Country of Orgin
NYI-DO	NY	568069	Oranges	9,510	9,380	1,730	Italy
"	"	568070	"	8.0	16.3	1.3	"
"	"	568071	"	7.1	14.1	1.8	"
NOL-DO	LA	610544	Limes	ND	-	-	Honduras
DAL-DO	TX	607615	Grapefruit	2,700*	12,160	985	Mexico
"	"	607611	"	4,400*	15,574	1,409	"
"	"	607614	Oranges	2,600*	7,474	1,232	"
"	"	507917	Limes	ND	-	-	"
"	"	507918	"	ND	-	-	"
"	"	607616	Oranges	10,800*	41,590	2,173	"
"	"	607617	"	11,100*	45,263	1,916	"
"	"	607618	"	3,100*	14,638	657	"
"	"	607623	Tangerines	6,700*	21,525	1,035	"
"	"	607624	Grapefruit	-	8,284	905	"
"	"	607627	Tangerines	8,700*	34,438	2,036	"
"	"	607632	"	12,000*	35,976	1,368	"
"	"	607633	"	11,000*	33,854	1,429	"
"	"	611401	"	13,700	-	-	"
"	"	611402	"	9,243	-	-	"
"	"	611403	"	7,652	-	-	"
"	"	611404	"	9,055	-	-	"
"	"	611405	"	7,496	-	-	"
"	"	611406	"	6,010	-	-	"
"	"	611408	"	10,860	-	-	"
"	"	607601	"	9,929	-	-	"
"	"	607602	"	8,693	-	-	"
"	"	607603	Oranges	9,249	-	-	"
"	"	611410	Tangerine	5,052	-	-	"
"	"	611411	Grapefruit	3,735	-	-	"
"	"	611409	Oranges	4,185	-	-	"
"	"	607604	Tangerine	2,987	-	-	"
"	"	607605	Lime	18	-	-	"
"	"	607606	Tangerine	6,732	-	-	"
"	"	607608	"	2,594	-	-	"
"	"	507884	Lime	ND	-	-	"
"	"	611418	"	ND	-	-	"

* Residue level in whole fruit calculated from levels found in peel and pulp.

TABLE 1 (continued)

Ethylene Dibromide (EDB) in Imported Citrus Fruits

Analyzing District	Collect. Location	Sample Number	Product	Parts per billion (ppb) EDB			Country of Orgin
				Whole	Peel	Pulp	
SJN-DO	PR	178966	Mandarine Orange	ND	-	-	Santo Dom
"	"	178965	Oranges	"	-	-	"
"	"	178967	Grapefruit	"	-	-	"
BUF-DO	NY	582067	Clementines	2,700	15,650	2,020	Spain
"	"	582071	"	16,100	25,260	6,250	"
"	"	582075	"	12,540	19,070	2,640	"
"	"	582076	"	7,830	8,900	830	"
NYI-DO	"	603596	"	269	1,030	139	"
"	"	603598	"	653	1,960	331	"
"	"	603597	Oranges	3,800	4,360	417	Israel
"	"	603599	Grapefruit	2,530	6,220	436	"
"	"	647926	Oranges	<1	-	-	Dom Rep
"	"	647927	Lemons	2.6	4.0	2.4	"

TABLE 2

Ethylene Dibromide (EDB) in Domestic Citrus Fruits

Analyzing District	Collect. Location	Sample Number	Product	Parts per billion (ppb) EDB Whole	Peel	Pulp	State of Orgin
SAN-DO	CA	312817	Oranges	ND	-	-	CA
"	"	312818	"	"	-	-	"
"	"	312819	"	"	-	-	"
"	"	312820	"	"	-	-	"
"	"	312822	"	"	-	-	"
"	"	312827	Lemons	"	-	-	"
"	"	312828	"	"	-	-	"
"	"	312829	"	"	-	-	"
"	"	312830	"	"	-	-	"
"	"	312831	"	"	-	-	"
MIN-DO	MN	299168	Tangelo	"	-	-	AZ
"	"	299169	Oranges	"	-	-	CA
"	"	299170	"	"	-	-	"
"	"	299171	Grapefruit	"	-	-	FL
"	"	299172	"	"	-	-	"
"	"	299173	"	"	-	-	"
"	"	299174	Oranges	"	-	-	CA
"	"	299175	Tangerines	"	-	-	"
"	"	299176	"	"	-	-	"
DAL-DO	TX	326883	Oranges	"	-	-	"
"	"	326884	"	"	-	-	"
"	"	301736	Tangelo	17.7	36.5	1.8	AZ
"	"	301737	Tangerine	19.2	41.3	2.3	"
"	"	326826	Grapefruit	1,515	2,208	338	FL
"	"	326827	Oranges	22.2	44.5	2.8	CA
"	"	326828	Grapefruit	ND	-	-	AZ
"	"	301738	Tangelo	"	-	-	"
"	"	301739	Tangerine	"	-	-	CA
"	"	301740	Grapefruit	"	-	-	AZ
"	"	292486	Oranges	"	-	-	"
"	"	292487	Grapefruit	"	-	-	"
"	"	292488	Oranges	"	-	-	"
"	"	292489	Grapefruit	"	-	-	"
"	"	292491	Oranges	"	-	-	"
"	"	292492	"	"	-	-	"
"	"	292493	Grapefruit	"	-	-	"
BLT-DO	MD	386994	"	"	-	-	FL
"	"	386995	"	"	-	-	"
"	"	386996	"	"	-	-	"
"	"	386997	Oranges	"	-	-	"
"	"	386998	"	"	-	-	"
"	"	386999	"	"	-	-	CA
"	"	387000	"	"	-	-	FL
"	"	361141	"	"	-	-	"

TABLE 2 (continued)

Ethylene Dibromide (EDB) in Domestic Citrus Fruits

Analyzing District	Collect. Location	Sample Number	Product	Parts per billion (ppb) EDB			State of Orgin
				Whole	Peel	Pulp	
SAN-DO	HI	325340	Oranges	1.3	5.9	ND	CA
"	"	325341	"	ND	-	-	"
"	"	325342	Grapefruit	"	-	-	"
"	"	325343	"	"	-	-	AZ
"	"	325344	Tangelo	"	-	-	"
"	"	325345	Tangerines	"	-	-	"
LOS-DO	AZ	354453	Oranges	"	-	-	CA/AZ
"	"	354451	"	"	-	-	"
"	CA	002748	"	1.2	<1	<1	FL
"	AZ	354452	"	ND	-	-	CA/AZ
"	"	354448	"	"	-	-	"
"	CA	002747	"	"	-	-	FL
"	"	002749	Grapefruit	110	70	40	"
"	"	002750	"	ND	-	-	"
"	"	002746	"	"	-	-	"
"	AZ	354449	Oranges	"	-	-	CA/AZ
"	"	354450	"	"	-	-	"
BOS-DO	MA	392272	"	"	-	-	FL
"	"	392273	"	"	-	-	CA
"	"	392274	"	"	-	-	"
"	"	377867	Tangelo	"	-	-	FL
"	"	377868	Tangerine	"	-	-	AZ
"	"	377869	"	"	-	-	FL
"	"	400981	Grapefruit	"	-	-	"
"	"	400982	"	"	-	-	"
"	"	400983	"	"	-	-	"
ATL-RL	FL	356215	Oranges	"	-	-	"
"	"	356216	"	"	-	-	"
"	"	356217	"	"	-	-	"
SEA-DO	WA	397911	"	"	-	-	CA
"	"	397910	"	"	-	-	"
"	"	397913	Grapefruit	"	-	-	FL
"	"	397914	"	"	-	-	TX
"	"	397915	Tangelo	"	-	-	CA
"	"	397916	Tangerine	"	-	-	"
"	"	397917	Oranges	"	-	-	"
"	"	397918	Grapefruit	"	-	-	FL
"	"	397919	Tangerines	2.1	1.6	<1	CA

TABLE 3

Ethylene Dibromide in Imported Citrus Juices/Concentrates and Citrus Products

Analyzing District	Collect. Location	Sample Number	Product	ppb EDB	Country of Orgin
ATL-RL	FL	395316	Orange juice concentrate	ND	Brazil
"	"	395317	"	"	"
"	"	395318	"	"	"
"	"	395319	"	"	"
"	GA	597990	Canned Mandarin Oranges	"	Spain
NYI-DO	NY	645971	Lemon juice	"	Italy
"	"	647718	"	"	"
"	"	647719	"	"	"
BLT-DO	PA	540836	Orange juice concentrate	"	Brazil
DAL-DO	TX	507945	Frozen orange juice concentrate	"	Mexico
"	"	607629	Orange juice	"	"
"	"	607630	"	"	"
"	"	607622	Grapefruit sections	"	"
BLT-DO	PA	540837	Orange juice concentrate	"	Brazil
"	"	540838	"	"	"
"	"	540839	"	"	"
LOS-DO	CA	002736	Orange juice concentrate	"	"
"	"	002738	"	"	"
"	"	002735	"	"	"
"	"	002734	"	"	"
"	"	002730	"	"	"
"	"	002732	"	"	"
"	"	002731	"	"	"
"	"	002733	"	"	"
"	"	002737	"	"	"
DAL-DO	TX	507985	"	"	Mexico
BOS-DO	MA	503192	Orange drink	"	Azores
DET-DO	MI	547977	Orange juice concentrate	"	Canada
"	"	547978	"	"	"
"	"	547979	Grapefruit juice concentrate	"	"
BUF-DO	NY	582892	Citrus fruit salad	"	"
"	"	582893	Grapefruit sections	"	"

TABLE 4

Assignment - EDB in Domestic Citrus Juices/Concentrates

Analyzing District	Collect. Location	Sample Number	Product	ppb EDB	State of Orgin
ATL-DO	ORL	271905	Orange juice concentrate	ND	Florida
"	"	271906	"	"	"
"	"	271907	"	"	"
"	"	271908	"	"	"
"	"	374584	Grapefruit juice concentrate	"	"
"	"	374585	"	"	"
"	"	374586	"	"	"
"	"	374587	"	"	"
DAL-DO	TX	292110	Orange juice concentrate	"	*
"	"	292111	"	"	*
"	"	292112	"	"	*
"	"	292113	"	"	*
"	"	292114	Grapefruit juice concentrate	"	*
"	"	292115	"	"	*
"	"	292116	"	"	*
"	"	292117	"	"	*

* Unknown, but assumed to be Texas.

2/84

CURRENT STATUS OF THE GRAIN FUMIGANTS

Aluminum Phosphide

Registration Standard was issued in October, 1981. This chemical was classified for restricted use based on its potential inhalation hazard.

Registration Standards recently issued for aluminum phosphide and magnesium phosphide required submission of product chemistry, characterization of the residue, reentry, volatility and hydrolysis studies. Toxicology studies are not being required pending the outcome of the residue study. A number of these studies have been submitted and reviewed. The data requirements, submitted studies and results of reviews are itemized in the attached tables.

Carbon Disulfide

Referred for RPAR review based on the acute toxicity and mutagenicity risk triggers.

Proposed for restricted use by regulation in August, 1979. Final classification rule has been written and the administrative steps necessary for promulgation have begun. The basis for restriction was the accident history - inhalation hazard.

Carbon Tetrachloride

Accepted for RPAR review on July 17, 1978, because the criterion for oncogenicity were exceeded. PD-1 was issued in October, 1980.

Proposed for restricted use by regulation in October, 1983. Final classification rule has been written and the administrative steps necessary for promulgation have begun. The basis for restriction was the accident history - inhalation hazard.

Chloroform

Accepted for RPAR review because the criterion for oncogenicity were exceeded. PD-2 was issued in September, 1982. This chemical was returned to the registration process in December, 1982. According to the limited data available, dietary exposure and the resulting cancer risk appear to be low. The PD-2 states that the registrant will be required to submit a petition to establish tolerances for chloroform.

Proposed for restricted use by regulation in October, 1983. Final classification rule has been written and the administrative steps necessary for promulgation have begun. The basis for restriction was the accident history - inhalation hazard.

Chloropicrin

A Registration Standard was issued in October, 1982. The requested exposure data is expected to be submitted in 1984.

Classification: Restricted use on all formulations greater than 2% on all uses because of acute inhalation toxicity, and of the hazard to non-target organisms. All formulations 2% and less for outdoor uses (other than rodent control) are unclassified.

Ethylene Dichloride

Accepted for RPAR review on 4/20/78; Risk trigger: oncogenicity.

Data Call-in Notice issued 7/81 requested chronic toxicity data on teratology and reproduction. Data requirements have now been satisfied.

Classification: Proposed for restricted use by regulation in October, 1983. Final classification rule has been written and the administrative steps necessary for promulgation have begun. The basis for restriction was the accident history - inhalation hazard.

Magnesium Phosphide

Registration Standard issued 2/82. See aluminum phosphide.

Methyl Bromide

Accepted for RPAR review on 8/80; Risk trigger: suspected oncogenicity Data Call-in letter issued 7/81. Time extension of 1 $^1/2$ years granted to the Dutch government for the oncogenic and reproductive testing. Requested studies on oncogenicity are due January 1987 and reproduction January 1986.

Classification: Restricted use on all formulations in containers greater than 1.5 lb.

Sulfur Dioxide

Classification: Proposed for restricted use by regulation in October, 1983. Final classification rule has been written and the administrative steps necessary for promulgation have begun. The basis for restriction was the accident history - inhalation hazard.

Statement of
Kenneth A. Gilles, Ph.D.
Administrator
Federal Grain Inspection Service
United States Department of Agriculture

Before The

Subcommittee on Toxic Substances and Environmental Oversight
Friday, January 27, 1984

Mr. Chairman and Members of the Committee:

We welcome this opportunity to discuss the pesticide, ethylene dibromide (EDB). We want to point out some general facts about EDB and then address its use as a grain fumigant in more detail.

Ethylene dibromide has been produced since 1923 and registered for use as a pesticide since 1948. In 1974, the National Cancer Institute issued a preliminary notice that EDB appeared to cause cancer in some laboratory animals at relatively high dosage levels. In December 1977, EPA began a review of risks and benefits and issued a statement which described the health risks of EDB. EPA continued to monitor EDB, and in June 1983 it found ground water in California had been contaminated by EDB. Shortly thereafter, wells in Hawaii and Florida were also found to have been contaminated, leading EPA to issue an emergency suspension of EDB as a soil fumigant.

EDB is a halogenated hydrocarbon used primarily as an additive in leaded gasoline. Annual EDB production is estimated at 300 million pounds. More than 90 percent is used in gasoline as an additive to prevent lead deposits in internal combustion engines. In 1983, approximately 5 to 7 percent was used for agricultural purposes.

A principal agricultural use of EDB was for soil fumigation to protect crops such as peanuts, soybeans, vegetables, and pineapples from nematodes until this use was suspended by the EPA in September 1983.

EDB has also been used as an on-farm grain fumigant and to rid grain elevators and milling equipment of insects. Current information indicates these uses have been decreased significantly. The National Grain and Feed Association, North American Grain Export Association and Millers National Federation have indicated that their member organizations have voluntarily stopped using EDB.

Quarantine treatment is required for fruits and vegetables exposed to fruit flies. EDB is a chemical fumigant used for postharvest control of Mediterranean, Mexican, Oriental, melon, and Caribbean fruit flies. There is no alternate effective treatment that will provide American agriculture the protection necessary to prevent the spread of all these destructive pests in all commodities and markets. Most citrus fruits from Texas and Mexico must be fumigated with EDB prior to their being shipped to California, Arizona, Texas, and Japan. California accepts Florida fruit fumigated with methyl bromide, but the other States and Japan require EDB fumigation. The loss of EDB would seriously affect the commerce of the domestic growers in the United States as well as many foreign countries, resulting in large economic losses. Less than 100,000 pounds of the chemical is used for this purpose domestically, which represents 0.3 percent of the total annual U.S. production of EDB.

USDA believes that alternatives are available to EDB for soil fumigation, grain treatment and spot mill fumigation, although some of these alternatives are not as effective or economical as EDB itself. However, as stated above, consistently effective alternatives to EDB are not available at this time for fruit and vegetable quarantine treatment. USDA has for a number of years been cooperating with industry and States to test alternative technologies to control fruit flies in the impacted commodities. This has resulted in Japan and California approving a cold treatment procedure on grapefruits from Florida. However, other citrus and tropical fruits will require separate technologies for each pest and commodity. Another nonchemical approach, currently employed in Texas, and under development in Florida for intra-state shipments, is the management of fruit flies in the field through the use of sterile flies and detection activities that will lead to a certification of freedom from infestation. Research is continuing to evaluate other chemical fumigants, various temperature exposures, and mixtures of gases.

During fiscal year 1983, approximately 393 million metric tons of grain was produced in the United States. During the same period, 176 million metric tons in domestic commerce were voluntarily inspected under the authority of the U.S. Grain Standards Act and 114 million metric tons were mandatorily inspected for export use. Under the Official United States Standards for Grain, the presence of live insects injurious to stored grain causes the grain to be graded, "weevily", which lowers the market value of the grain. Fumigants are used to kill the insects so the grain will not be graded as "weevily." Insects in grain constitute a potential public health as well as economic problems.

There has been considerable publicity concerning the amount of United States grain in storage that contains EDB. A team consisting of officials from USDA, EPA, and States determined, through an assessment report in 1980, that only 2-5 percent of the grain in storage had been fumigated with formulations containing EDB. We must recognize that grain is commingled during transportation and marketing (Attachment A). This blending of EDB treated grain with non-treated grain could increase the percentage of the total grain supply which contains detectable traces of EDB.

Considerable speculation has been given to the level of EDB residues in fumigated grain. Thirty grain samples were collected from our Board of Appeals and Review office in Kansas City and sent to a Food Safety Inspection Service laboratory in St. Louis for analysis. These samples originated in several different locations. The preliminary findings follow:

Grain	No. of Samples	Parts Per Billion (PPB)
Wheat	6	ND 1/
Wheat	1	2
Wheat	2	10
Wheat	1	22
Corn	9	ND
Corn	1	2.5
Sorghum	5	ND
Sorghum	1	2.2
Sorghum	1	6.7
Barley	1	1.1
Barley	1	6.5
Oats	1	ND

1/ ND means none detected.

Of the 30 samples, EDB was not detected in 21 and the nine remaining samples averaged less than six PPB. A more complete description of the information is attached to this statement, including the class of wheat and the originating

FGIS Field Office (Attachment B). Because of the vast area covered by each field office and the complexities of grain transportation, no definite conclusions can be made concerning the origin of the grain or the application, source, or type of fumigants applied.

USDA has shared the above information with EPA and is presently cooperating with EPA in the testing of 400 additional samples (200 corn and 200 wheat) taken from 15 field offices. Samples were collected in proportion to the grain exported from each location during fiscal year 1983. Each sample represents approximately 60,000 bushels of grain. These samples are now being received and analyzed, and results will be given to EPA by January 31.

In addition to the USDA tests, the EPA laboratory at Beltsville also has received a portion of each sample and plans to test approximately 20 percent of them as a quality assurance procedure. These samples are not statistically representative of the total grain in storage.

Our sources indicate that very little EDB presently is being used commercially in liquid grain fumigants. Most of the liquid fumigants contain from one to five percent EDB and are distributed in one and five gallon containers which suggests usage in small quantities for farm-stored grain. The grain industry contends that it is not using EDB as a fumigant.

To eliminate public concern about EDB in the Nation's food supply, to avoid disruption of the food distribution system, and to avoid economic hardship for those who have grain previously fumigated with liquid fumigants containing traces of EDB or who currently may not have a satisfactory alternative for on-farm fumigation, it may be appropriate for EPA to establish reasonable, interim guidelines based on data derived from the USDA, EPA, and other sources such as the grain and milling industries and the Grocery Manufacturers of America.

To further assist the EPA, a protocol has been planned with EPA, and ARS to determine the fate of EDB during corn processing. This work will be completed by September.

This concludes my prepared statement. My colleagues and I will be happy to respond to your questions.

Attachments

ATTACHMENT A

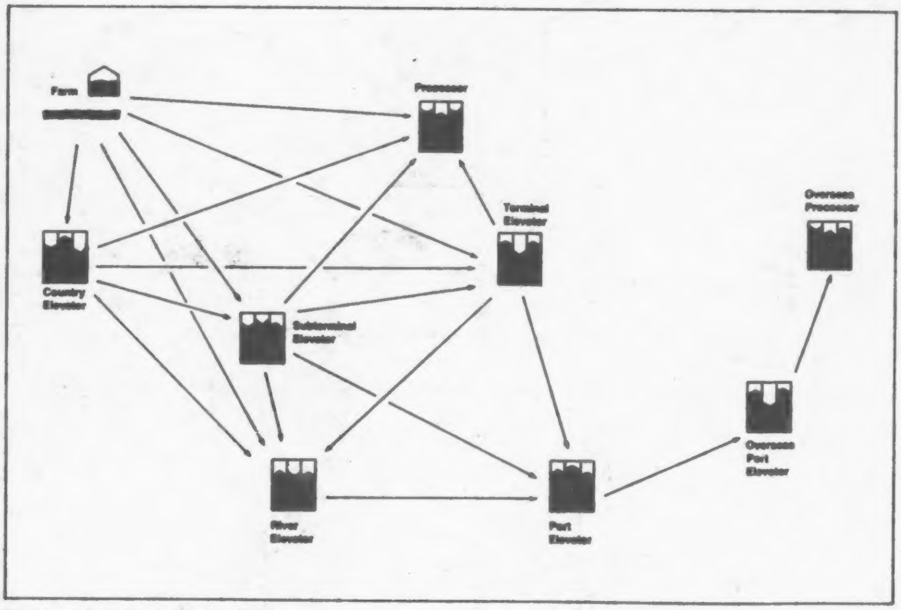

Figure 1.—General flow of grain from the farm through the system.

Farm Operations

The basic operations performed at the farm are harvesting, drying, aerating, storing, and outloading, as shown schematically in figure 2. However, all those operations might not necessarily be performed at a particular farm.

Starting from the left of the illustration, grain in the field is cut and the kernels of grain separated out by means of a combine which can be fitted with a collection head suited to the particular type of grain being harvested. The combine has a storage tank on board from which accumulated grain is periodically transferred to a truck or wagon and then shoveled or discharged by gravity into a pit.

Grain is moved from the bottom of the pit by auger to the boot of a bucket elevator that hoists the grain to a height from which it flows by gravity to a storage bin; or the grain may be diverted through a dryer and aeration bin before going to storage. Portable flight elevators and augers may also be used to hoist grain.[2]

Wheat and soybeans usually do not require drying, whereas corn harvested by combine must be dried from about 25 percent moisture down to about 14 percent moisture before being placed in storage. Without such drying, high-moisture corn would deteriorate rapidly in storage.

Country Elevator Operations

Figure 3 illustrates the operations performed at the country elevator. A sample extracted from incoming grain is checked for a number of factors related to quality, including moisture, test weight, damage, shrinkage and breakage of kernels, infestation, adulteration, odor, and often protein content. The grain is then weighed and unloaded into a pit, with a steel grate over the pit serving to remove sticks of wood, corn cobs, and other coarse material.

From the pit, grain is transferred by screw conveyor or gravity to a bucket elevator and then by gravity into a storage bin; or the grain can be sent through a cleaner or dryer, or both, before going to storage. The term "cleaner" as used in this report includes screener, shaker, vibrator, scalper, and separator or other similar equipment used to remove foreign material and particles which are appreciably smaller, larger, or of a different density than desired.

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[2] Planning Grain-Feed Handling for Livestock and Cash-Grain Farms, MWPS-13, 1968, Midwest Plan Service, Iowa State University, Ames, Iowa 50010.

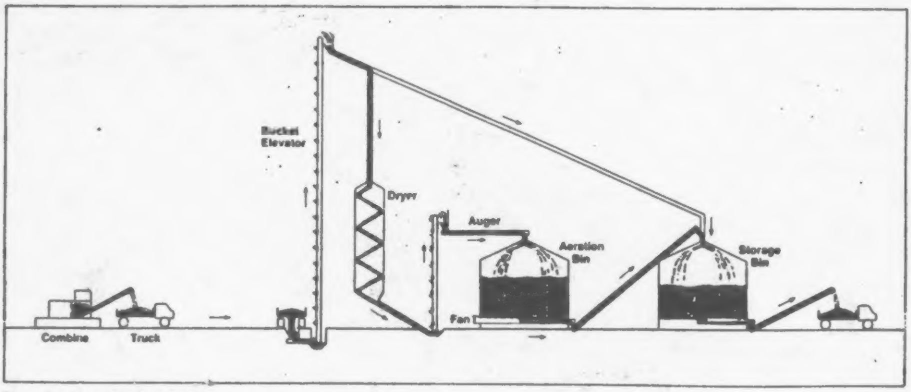
Bucket Elevator
Dryer
Auger
Aeration Bin
Storage Bin
Fan
Combine
Truck

Figure 2.—Flow of grain at the farm.

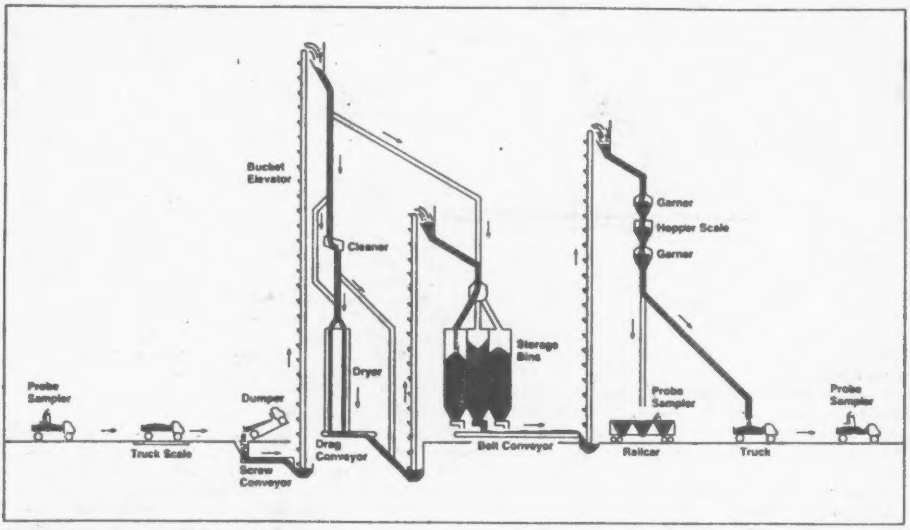
Bucket Elevator
Cleaner
Dryer
Storage Bins
Garner
Hopper Scale
Garner
Probe Sampler
Truck Scale
Dumper
Screw Conveyor
Drag Conveyor
Belt Conveyor
Probe Sampler
Railcar
Truck
Probe Sampler

Figure 3.—Flow of grain through the country elevator.

For outgoing shipment, grain can be drawn from several different bins in required percentages to obtain a desired grade. Grain is moved from the bins by gravity, belt, screw conveyor, or drag (chain) conveyor to a bucket elevator, which in turn discharges the grain for flow by gravity into a hopper scale. To maintain essentially continuous flow, a garner is positioned above the scale to serve as an accumulator; another garner is positioned below the scale to handle the surge of grain when the gate at the bottom of the scale is opened. Outgoing shipments are also sampled.

Other Types of Domestic Elevators

Subterminal, terminal, river, and port elevators in the United States are essentially alike in that they all unload, weigh, sample, store, blend, and load out grain. They also have capability for cleaning and drying grain and can treat grain for insect infestation. Because of the likeness of operations among these elevators, only one type—the port elevator—is described here.

Attachment B

EDB Residue Tests by FSIS

Preliminary Results

FSIS ID	Grain	Originating Office	Results
1G-59	HRS wheat	Minneapolis	10 ppb
2G-59	HRS wheat	Grand Forks	ND 1/
3G-59	Durum wheat	Grand Forks	ND
4G-59	SRW wheat	Indianapolis	10 ppb
5G-59	SRW wheat	Indianapolis	22 ppb
6G-59	HRW wheat	Portland	ND
7G-59	HRW wheat	Galveston	2 ppb
8G-59	HRW wheat	Galveston	ND
9G-59	HRW wheat	Pasadena	ND
10G-59	HRW wheat	Pasadena	ND
11G-59	Yellow Corn	Minneapolis	ND
12G-59	Yellow Corn	Wichita	ND
13G-59	Yellow Corn	Baltimore	ND
14G-59	Yellow Corn	Cedar Rapids	ND
15G-59	Yellow Corn	Peoria	ND
16G-59	Yellow Corn	Peoria	ND
17G-59	Yellow Corn	St. Louis	ND
18G-59	Yellow Corn	Omaha	ND
19G-59	Yellow Corn	Omaha	2.5 ppb
20G-59	Yellow Corn	Peoria	ND
21G-59	Sorghum	Wichita	ND
22G-59	Sorghum	Omaha	6.7 ppb
23G-59	Sorghum	Omaha	2.2 ppb
24G-59	Sorghum	Plainview	ND
25G-59	Sorghum	Destrehan	ND
26G-59	Sorghum	Destrehan	ND
27G-59	Sorghum	Pasadena	ND
28G-59	Barley	Montreal	1.1 ppb
29G-59	Barley	Montreal	6.5 ppb
30G-59	Oats	Duluth	ND

United States
Department of
Agriculture

Washington, DC
20250

March 7, 1984

Honorable Dave Durenberger
Chairman, Subcommittee on Toxic
  Substances and Environmental Oversight
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This is in response to your letter of February 10, 1984, requesting a written response to questions raised at the hearing on ethylene dibromide (EDB). Our response to those questions is enclosed.

We appreciate the opportunity to provide you with this additional information.

Sincerely,

K. A. Gilles

Kenneth Gilles
Administrator
Federal Grain Inspection
  Service

Enclosure

Ethylene Dibromide Questions and Answers

1. Has the U.S. Department of Agriculture ever performed any risk assessment studies involving Federal grain inspectors to determine if they are being exposed to unacceptable levels of EDB? Carbon tetrachloride? Any other fumigants or pesticides that might leave residues?

In July 1983, the Federal Grain Inspection Service (FGIS) requested that the National Institute of Occupational Safety and Health (NIOSH) conduct a health hazard evaluation of the Portland, Oregon, field office. The Portland office was chosen for this study because of higher than average FGIS employee exposure to potentially fumigated grain. In February 1984, NIOSH published an interim report indicating that FGIS employee exposure to fumigants was well below permissible levels.

2. (a) What are the primary sources of imported citrus for the United States?

Mexico is the primary source for imported citrus fruit. Very small quantities are received occasionally from Morocco, Spain, and Japan. The Japanese citrus is not fumigated.

(b) What percentage of the U.S. citrus market consists of imported citrus?

It is estimated that imported citrus treated with EDB constitutes about 2 percent of the U.S. citrus market. Limes and lemons do not require treatment as a condition of entry.

(c) What regions of this country receive most of the imported Mexican citrus, and in what seasons is it imported?

Since imported fruit is frequently repacked on arrival in the United States and becomes involved in a very complicated marketing system, it is difficult to determine the distribution of Mexican citrus in the United States. It is reported that much of this product winds up in California.

(d) How much citrus has been imported in each of the past 5 years, and what quantities are anticipated to be imported in the coming year as a result of winter damage to domestic orchards?

Data on imports is readily available only for Fiscal Year 1982-1983. We do not expect a significant increase in imports as a result of winter damage since Mexico is the biggest exporter and this country also suffered damage.

(e) Is fumigated imported citrus used in the production of orange or grapefruit juice, juice concentrates, or other consumer products prepared either in this country or abroad?

To our knowledge all of the fumigated imported citrus is marketed as whole fruit and is not used for juice concentrates or other consumer products.

3. (a) What sort of assistance and/or supervision does the USDA provide foreign nations in their fumigation of citrus bound for the United States?

All fruit which requires an EDB fumigation to meet U.S. entry requirements is normally fumigated by U.S. personnel or under the supervision of U.S. personnel in the country of origin. Assistance is in the form of information which informs the foreign government or exporter of fumigation facility standards.

(b) How many fumigation locations are there, and how many USDA personnel monitor those centers?

There are approximately 60 fumigation facilities the majority of which are in Mexico. Approximately 30 USDA employees directly supervise or indirectly monitor the facilities.

(c) What is the nature of and frequency of inspection or supervision of each center?

All new facilities must be tested to assure that they meet established USDA standards. Prior to the fumigation season, each facility is reinspected and the first treatment is monitored by USDA supervisors. After each additional 15 fumigations, the facility is reinspected by USDA inspectors. All personnel who supervise treatments receive mandatory fumigation training and are certified pest applicators.

4. (a) Besides citrus, are there any other imported fruits or vegetables subject to EDB quarantine fumigation?

Several fruits other than citrus are subject to EDB quarantine treatment. However, the largest volume of items is mangoes and papayas.

(b) Please provide available information about EDB contaminant levels on these fruits and vegetables.

The Food and Drug Administration is responsible for determining residue levels on imported commodities. Thus, the Animal and Plant Health Inspection Service is unable to provide the requested information.

5. (a) How much is known about EDB's primary chemical alternative methyl bromide?

There are four major use categories of methyl bromide in agriculture: (a) soilfumigation for control of nematodes, insects, weeds, and fungi; (b) fumigationof dry foodstuffs, particularly produce in bags or packages, for insect control; (c) quarantine fumigation of fruit, vegetables, seeds and plants for insects; and (d) fumigation of structures such as barns or storage bins to eradicate pest infestations. A summary of specific uses is attached.

Methyl bromide is applied as a gas only by trained operators using protective clothing to prevent exposure. Detailed information on the worker precautions necessary are available from the U.S. Environmental Protection Agency.

Methyl bromide is not the primary alternative to EDB in all cases since its high volatility and/or toxic side effects to nontarget organisms prevent its use.

Data pertaining to potential human toxicological risk is maintained by the Environmental Protection Agency.

(b) How widely is it used as a fumigant?

The Environmental Protection Agency maintains information on pesticide use which is supplied by the product registrants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These data are sometimes filed as confidential business information and are not available to the Department of Agriculture.

(c) Are there other insecticidal uses for methyl bromide of which USDA is aware?

The Environmental Protection Agency has permitted methyl bromide use for a number of commodities identified in question 5a. See the attached summary for additional uses on a number of commodities and locations.

6. What efforts have APHIS and USDA in general made to convince the Japanese of alternatives to EDB fumigation of grapefruit and other American citrus that they import? What alternative quarantine methods have been tried?

APHIS has had and continues to have bilateral discussions with the Japanese Government quarantine officials regarding EDB and other acceptable alternative treatments. APHIS has provided data on cold treatment as an alternative. The Japanese Government has accepted cold treatment as an alternative provided an APHIS employee certifices that the treatment en route was successfully completed upon arrival in Japan.

7. What is the value of the citrus export market to Japan? What is the total value of the U.S. citrus export market?

The value of U.S. citrus exports to Japan is estimated at $117 million. While no figure is available for the value of total U.S. exports, Japan accounts for more than 90 percent of the U.S. export market.

application summary

commodity fumigation

	Tolerance (ppm)	Dosage (lbs./1000 cu. ft.)	Exposure Time (hrs.)
Almonds	200	3.5	24
Apples	5	5	2
Apricots	20	5	2
Barley	50	4	12
Barley	50	3	24
Beans, all	50	3.5	24
Beets	30	3	4
Brazil nuts	200	3.5	24
Bushnuts	200	3.5	24
Butternuts	200	3.5	24
Cabbage	50	4	4
Cantaloupes	20	2.5	2
Carrots	30	4	4
Cashews	200	3.5	24
Cherries	20	5	2
Chestnuts	200	6	6
Chestnuts	200	3.5	24
Cipollini bulbs	50	4	4
Citron	30	3	2
Cocoa beans	50	1.5	12(a)
Copra	100	2.5	24
Corn	50	2	24
Corn	50	4	12
Cottonseed	200	6	24
Cucumbers	30	2.5	4
Dates (dried)	125	1	24
Eggplants	20	3	4
Figs (dried)	250	1	12
Filberts	200	3.5	24
Garlic	50	3	4
Grapefruit	30	3	2
Grapes	20	4	2
Hay (alfalfa)	50	3	24
Hickory nuts	200	3.5	24
Honeydew melons	20	2.5	2
Horseradish	30	3	4
Jerusalem artichokes	30	3.5	4
Kumquat	30	3	2
Lemons	30	3	2
Limes	30	3	2
Muskmelons	20	2.5	2
Nectarines	20	5	2
Oats	50	3	24
Oats	50	6	12(b)
Okra	30	3.5	2(c)
Onions	20	3	6
Oranges	30	3	2
Parsnips	30	3	4
Peaches	20	5	2
Peanuts	200	3.5	24
Pears	5	5	2
Peas (with pods)	50	3	2
Peas (dried)	125	4	24
Pecans	200	3.5	24
Peppers	30	4	2
Pimentos	30	2.5	3
Pineapples	20	2	4
Pistachio nuts	200	3.5	24
Plums	20	5	2
Popcorn	240	1.5	2(a)
Potatoes	75	3	6
Prunes	20	5	2
Pumpkins	20	2.5	2
Quinces	5	5	2
Radishes	30	3	4
Rice	50	3	24
Rice	50	6	12(b)
Rutabagas	30	3	6
Rye	50	3	24
Rye	60	6	12(b)
Salsify roots	30	3	4
Sorghum (grain)	50	4	24
Sorghum (grain)	50	6	12(b)
Spices	400	3	12
Squash, Summer	30	4	2
Squash, Winter	20	4	2
Squash, Zucchini	20	2.5	3
Sugar beets	30	3	4
Sweet corn	50	3	4
Sweet potatoes	75	3.5	4
Tangelos	30	3	2
Tangerines	30	3	2
Tomatoes	20	3	4
Turnips	30	3	4
Walnuts	200	3.5	24
Watermelons	20	2.5	2
Wheat	60	3	24
Wheat	60	6	12(b)
Yams	30	3.5	4

(a) Chamber
(b) Khapra beetle quarantine
(c) Pink bollworm quarantine

agricultural premises fumigation

	Tolerance (ppm)	Dosage (lbs./1000 cu. ft., unless otherwise indicated)	Exposure Time (hrs.)
Ant colonies	NF*	1 lb./colony	—
Barns	NF	3	24
Feed rooms	NF	3	24
Grain bins	NF	3	24
Greenhouses	NF	3	4
Greenhouses	NF	5	48(b)
Mushroom houses	NF	2	24
Poultry houses	NF	3	24

space fumigation

	Tolerance (ppm)	Dosage (lbs./1000 cu. ft.)	Exposure Time (hrs.)
Bags†	NF	11	24
Boxes†	NF	11	24
Crates†	NF	11	24

soil fumigation

	Tolerance (ppm)	Dosage lbs./Acre	Exposure Time (hrs.)
Fruit tree sites	NF	412	48
Plant beds (for production of transplants only)	NF	872	24
Strawberries	30	240	48
Tobacco	NF	872	48
Tomatoes	40	240	48

*Non-food

†For harvesting or storing raw agricultural commodities.

STATEMENT OF

RON D. WHITE

Assistant Commissioner
Regulatory Division

TEXAS DEPARTMENT OF AGRICULTURE

Before
Subcommittee on Toxic Substances and Environmental Oversight
of the U. S. Senate Committee on
Environment and Public Works

January 27,1984

Mr. Chairman, members of the committee, my name is Ron White; I am Assistant Commissioner, Regulatory Division, of the Texas Department of Agriculture.

Concern over ethylene dibromide is not a new issue in Texas. Since 1980, Texas has had in operation a sterile fruit fly program that has reduced by more than 80 percent the amount of EDB used to fumigate citrus. The concern in Texas was not only over the health effects of EDB, but also over the expense of using the product. The sterile fly program saved our citrus producers over $500,000 last year alone.

For the 1983-84 season, suspending the use of EDB will have no effect on the Texas citrus industry. There will be no effect, since there is no more fruit to be shipped from Texas because of the severe freezes that have occurred in the past month. There is likely to be permanent damage to our citrus industry, and land which is now in citrus may well be shifted to other crops. The latest information we have is that perhaps as many as one fourth of the trees have been killed by the freezes. All this and the coldest part of winter is still ahead of us.

Immediate suspension of use would have only small effect in the near future as well because of the success of the sterile fruit fly program. Developed by the Texas citrus industry, the Texas Department of Agriculture, the USDA and others, the program controls fruit flies through the release of sterile Mexican fruit flies along with a careful program of insect trapping and fruit cutting. This program leaves EDB for the last resort, and last year, for example, ninety-eight percent of the fruit was shipped without fumigation. In short, this program succeeded in displacing more than 15,000 pounds of EDB, saving our growers about $500,000 in fumigation costs, and, even more important, reduced health risks to workers and consumers alike.

This program works because we have an agreement with California and Florida, monitored by the USDA, calling on us to trap flies, cut fruit and try to find larvae, and release sterile flies on pre-arranged schedules to keep the fly population in check. The program was modified this year, based on USDA experimental data, to include a provision which calls for malathion to be sprayed in areas immediately adjacent to insect finds. Everyone wanted to get by without EDB this year, for both cost and health reasons.

Whether or not we would have made it is a difficult question to answer, since the freeze has completely destroyed the citrus crop, but I believe it could have been done. By carefully selecting fruit which was to have been shipped to California and Florida from parts of our growing area which did not have flies, I think it could have been accomplished. This would have been the second year in which we would have had a very abundant crop and that enters as an important issue because we do have some problem with fruit being left on the trees or on the ground in the groves, providing a habitat for the fly. In short, we have a need to improve the cultural practices of some growers as well. TDA was considering actions, in meetings with our growers, when the freeze came and made such activities moot.

Late last year, our concern over EDB expanded to include a variety of grain based products on grocery store shelves. The Texas Department of Agriculture tested over 100 grain-based products and discovered EDB residues over one part per billion in about one out of every three products tested.

We began our testing process immediately after Florida announced its test results. I was, frankly, surprised to read in my Saturday morning paper on December 10 of the levels of EDB residues discovered in grocery products being sold in Florida, especially considering earlier assurances that EDB dissipated rapidly and would not show up at the grocery store. I was additionally concerned to learn that the food manufacturers said they intended to sell in other states the products removed from the shelves in Florida. I made a note right then to check into this, and on the following Monday, we started our tests.

There are two points to notice in the test results from Florida and

Texas. The first is that one out of every three products tested contained EDB residues higher than one part per billion, with residue in one product, Duncan Hines Bran Muffin Mix, reaching 436 parts per billion. The second point is that at least two out of every three products tested reached the shelves at a competitive price free of any EDB contamination, proving not only that it is possible to get an EDB-free product to market, but that the great majority are already getting to market without this chemical.

Our tests in Texas also determined that, contrary to some claims, not all EDB residues dissipate during the cooking process. At the request of the Environmental Protection Agency, we conducted cooking tests on seven products, and discovered that some EDB residues remained in three of those products. Our testing process is continuing, and we are currently gathering samples of grain-based products being used in school lunch programs across the state.

The results of these tests have met overwhelming interest from the public in Texas. We received over 2,000 telephone calls from individuals seeking to avoid products containing EDB. We provided them with lists of our test results, and our test results were printed in newspapers across the state, while at the same time we cautioned the public that EDB contamination in grain products is not brand specific. With the exception of a very few products marketed mainly in health food stores, the consumer is unable to knowingly purchase products that do not contain EDB or to avoid those which do.

It did not help that we reassured the public at each opportunity that the risks associated with EDB develop over a long period of time, that another bowl of grits won't kill anyone. The public was quick to remind us that this chemical has been used in their food already for more than twenty five years, and that its carcinogenic effects have been documented for more than a decade. The overwhelming consensus of those two thousand callers was that they had taken the risks associated with EDB long enough, and they weren't going to take them any more.

There are those who will insist, and they will insist to you today, that this consumer reaction is just panic, that the public needs reassurances more than decisive action. They are wrong. The general public is looking to state and federal officials for action that will insure that their food supply is safe, and instead they have witnessed a ridiculous spectacle of industry officials and bureaucrats quibbling over just how many parts per billion of a deadly chemical will cause just how many deaths from cancer. There is no panic by consumers. We are seeing instead consumers who are indignant that they are expected to risk their very lives while the argument continues, not over what level of EDB is safe, but over whether any level should be allowed in the public food supply. There is no panic, but there is a growing anger that stronger, quicker action has not been taken to protect their food supply.

Similar concerns have been expressed by farmers in our state. We contacted the grain producers organizations when we first began to look into this situation, and learned that EDB was not widely used in Texas. We have not re-registered the product for use in Texas in 1984, and that decision has met no protest. Our farmers have worked long and hard to build a reputation for producing good, high quality healthy products, and it is in their interest to maintain that reputation, because by doing so, they protect and enhance their markets. They produce commodities that are good for U.S. consumers and foreign buyers alike, and it is important for that goodness not to get diluted after it leaves our farmers' hands.

There is also a larger question here that I want to address. Next year at this time there may well be another hearing just like this about another pesticide. There is no reason to think it won't happen, because there are a lot of pesticides now in use which have never had the proper scientific work done on them. These products were grandfathered into the system when FIFRA was passed, and the scientific work which supports their use is to varying degrees inadequate. This problem has been smouldering at EPA for a number of years. Unfortunately, when the fire breaks out, it doesn't happen at the EPA offices in Washington. It explodes in Texas, in New Jersey, in Florida, affecting citizens who believe the products to be safe when used according to EPA-approved directions.

Last August a farmworker died in Texas from acute Dinitro poisoning. The active ingredient is dinoseb, a chemical that has been around a long time. Some of the data supporting its continued registrations was done by IBT. The label, which had been approved by EPA, did not contain warnings about protective clothing and contained misleading medical advice, which cost that man his life.

Texas does not have, nor does any other state, the resources tc handle registration. But EPA has never taken it seriously, in my judgement, and people who use these products are being exposed to unknown risks and some of those risks are very large indeed.

Two things are needed to correct this problem. First, you need a commitment from EPA to organize its activities to get the work done. Second, you have to give them the resources they need to accomplish the task.

Failing this, you never know just when the next screamer is going to arise. There are a number of candidates out there, a real backlog of scientific work to be done. This work will only be accomplished by a plainly written amendment to FIFRA that sets a non-negotiable time-table for accomplishing the necessary work, and provides sufficient funding to get the work done.

I have heard the arguments about the loss of useful pesticides to the farmers and, as I see it, the situation right now is the one that is most likely to disrupt things. There is a lot of uncertainty, partly because no one other than EPA's technical people takes the RPAR process seriously. As a result, we find ourselves quibbling about relative levels of a known carcinogen and trying to estimate the economic costs associated with banning the product. If there was some certainty about the RPAR process, then the economic cost--by the time the process comes to this stage--would be reduced, because appropriate action would have been taken to find and use appropriate substitutes. In short, a very active reregistration program which is based on solid analysis carried out in public is in everyone's interest.

In conclusion, Mr. Chairman, I just want to reinforce the notion that the people I have talked to about this are indignant, and they are not in any sort of a panic. They want EDB out of their foood and they want to see something put in place that will prevent the sort of a spectacle they are witnessing from ever arising again. I do not believe that is too much to ask of government. We at the Texas Department of Agriculture have done everything within our power to get EDB out of the food supply, but it is a national problem. You cannot legally buy EDB in Texas today, but you can buy cornmeal or flour or muffin mix that is contaminated with EDB.

We stand ready to help you, EPA, and anyone else who wants to get this fixed.

WRITTEN TESTIMONY

OF

DOYLE CONNER

COMMISSIONER OF AGRICULTURE, STATE OF FLORIDA

TO THE

SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT

January 27, 1984

Thank you for this opportunity to appear before your committee and to share with the committee Florida's recent experiences with ethylene dibromide (EDB), even though the questions posed in your request for my appearance before your committee could best be answered by a representative of the Environmental Protection Agency.

EDB has been registered as a pesticide since 1948 and its current use is regulated by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act.

Initially the general consensus in the scientific and regulatory communities was that EDB, when applied according to label directions, would cause no adverse affects on the environment or human health. This consensus, at the time, was based on the prediction that the applied EDB would convert to a gaseous state and rapidly dissipate or break down in the environment to inorganic bromide, a relatively harmless chemical entity. Consequently in 1956, the responsible federal agency established inorganic bromide tolerances for a number of food products following treatment with EDB, either as a soil fumigant or as a post harvest application including grain storage and mill machinery fumigation. At the same time, organic bromide (E.G. parent EDB) residues in various grains and grain products were exempted from any tolerance requirements.

Since that time much information has evolved regarding the characteristics and ultimate impact of EDB on the environment as well as human health. In 1975, the National Cancer Institute (NCI) issued a preliminary notice that EDB appeared to induce cancer in laboratory animals. Further evidence presented in 1977 confirmed that EDB posed risks of producing tumors, genetic mutations and adverse reproductive effects. In 1978, NCI reported that a bio-carcinogeneses bioassay of EDB indicated that EDB, when orally administered, caused stomach cancer in rats and mice. During the interim and as late as September, 1983, EPA in their position documents have confirmed these conclusions.

Mr. Chairman, I would like to share with the committee our EDB problems, which commenced last summer.

On July 5, 1983, after news of recent findings of trace quantities of EDB in groundwater in the State of California, the first drinking water samples were drawn by Department of Agriculture and Consumer Services' personnel. These samples were collected and analyzed at my request even though the primary responsibility for groundwater does not come within the purview of this Department's authority to ascertain if any EDB residues were occurring in drinking water wells close to areas known to be treated with EDB in Florida. The initial analysis of one of these samples appeared to be positive and was subsequently confirmed by positively identifying the presence of EDB using the analytical technique of gas chromatography/mass spectrometry (GC/MS). From the evidence that began to mount, it became apparent that the previous predictions of the fate of EDB in the environment were no longer valid, particularly at the extremely low concentration levels detected by current analytical instruments. Following the detection of EDB in a number of drinking water wells, the Florida Department of Health and Rehabilitative Services suggested that users of wells containing EDB levels of .1 ppb should seek alternative sources of drinking water. This action by the Department of Health and Rehabilitative Services was dictated because of the absence of a federal tolerance for EDB in drinking water. Concurrently on September 16, I issued a temporary suspension on the distribution, sale and use of EDB as a soil fumigant in Florida. The temporary suspension was followed by a permanent suspension on October 7.

The discovery of trace quantities of EDB (parent compound) in drinking water samples caused concern among personnel of the Department of Agriculture and Consumer Services, the agency charged with the primary responsibility of enforcing the provisions of the Florida Food Law. Department personnel began to review federally registered uses of EDB which may have an adverse impact on the food chain.

Since EDB is federally registered for spot fumigation of grain-mill machinery and for fumigation of stored grain, a sampling and analysis program was initiated by my Department to randomly survey processed grain products and food products derived from animals which may have ingested grain fumigated with EDB.

On September 22, 1983, the first samples of food products were analyzed by Departmental personnel for possible EDB residues. Prior to this date our Chemical Residue Laboratory personnel had been heavily involved with analyzing water samples for EDB residues. This effort was in support of the Department of Health and Rehabilitative Services which is the lead agency for sampling for testing drinking water. From September 22, 1983 through November 16, 1983, a total of 92 food and feed product samples of various types were analyzed. Only one cornmeal sample, analyzed on October 31, 1983, and one wheat grain sample, analyzed on November 3, 1983, appeared to contain any traces of EDB (less than 1.0 ppb).

As a result of the detection of trace levels of EDB in the cornmeal and wheat grain samples, we began to intensify our efforts in looking for EDB residues in processed grain products, particularly corn products. From November 16, 1983 through December 14, 1983, an additional 53 products were collected and analyzed, including the 29 additional samples of corn products on which analysis and confirmation were completed during the week of December 5th. Fourteen of the 29 corn product samples contained EDB residues in excess of 1.0 ppb.

On December 5, 1983, I notified the Federal Food and Drug Administration (FDA) by Mail-O-Gram of our preliminary detection of EDB in a number of cornmeal, cornbread mix, and grits samples. In the absence of established federal tolerances for EDB, per se, in processed grain products, FDA was requested to advise us of their regulatory strategy in this situation. A copy of the Mail-O-Gram was sent to Region IV Office of the Federal Environmental Protection Agency (EPA) and at the same time an ongoing dialogue with representatives of the Department of Health and Rehabilitative Services (HRS) was initiated.

On December 8, 1983, we received FDA's response which advised that FDA could pursue regulatory action only if the inorganic bromide residues exceed the established tolerances. In order for them to consider regulatory action on the basis of the parent compound EDB, EPA would have to establish new EDB tolerances following revocation of existing regulations.

On this same day Dr. Stephen King, the State Health Officer, recommended to me that foods contaminated with EDB at a level equal to or more than one part per billion (1 ppb) should not be consumed by the public. On December 9, 1983, based on this recommendation and after two joint meetings during the day between representatives of the Department of Agriculture and Consumer Services, Department of Health and Rehabilitative Services, and the affected industry, the Department of Agriculture and Consumer Services initiated its first stop sale action ordering removal of 13 corn products from the marketplace. Department personnel began contacting retail and wholesale outlets immediately and worked throughout the weekend removing the affected products from trade channels.

During the ensuing weeks, as samples were collected, analyzed and confirmed, the Department issued four additional stop sale orders. These actions occurred on December 15, 20, and 28, 1983 and January 10, 1984. As of January 10, a total of 77 corn and flour products had been identified for removal from the marketplace out of a total of 273 food samples. These samples include grain products from 36 companies.

As you are probably aware, the regulatory actions taken by Florida, in the absence of federally established tolerances for the parent compound EDB in processed grain products, have been quite complex and controversial. On December 21, 1983, a joint letter to Mr. Ruckelshaus, EPA Administrator, from Governor Graham and myself urged that EPA should bring its considerable scientific and technical resources to bear on the EDB situation and act expeditiously in establishing current and relevant federal standards for EDB in foods. The Governor and I pointed out that the EDB problem was not Florida's alone, but one of national proportions because the majority of grain products found to be contaminated were imported into Florida from other states.

Subsequently, Governor Graham received an interim response from EPA in which they shared our concern and agreed that EPA should use its scientific and technical resources to carefully examine the EDB problem. EPA officials also advised that they, along with USDA and FDA officials, are working as quickly as possible to review the date from the State of Florida and the FDA and to examine all other pertinent data. EPA indicated that they expect that its collection and review of data will be completed shortly after the first of the year.

On December 29, 1983, representatives from the Department of Health and Rehabilitative Services and Department of Agriculture and Consumer Services met with EPA officials in Washington, D.C., to share Florida's most recent analytical results and to encourage them to establish interim tolerances for EDB in foods that could be used uniformly by all states. As a result of this meeting, EPA told Florida officials that it would recommend how much EDB residue should be allowed in foods and would attempt to make its recommendation by the end of January. We are hopeful that these recommendations are finalized as soon as possible.

On December 23, 1983, the Grocery Manufacturers of America (GMA) filed suit in federal court in Tallahassee seeking a temporary restraining order and other relief against the Department of Agriculture and Consumer Services and the Department of Health and Rehabilitative Services. The court denied GMA's request for such relief. On January 12 through 14 GMA petitioned the same court to issue a preliminary injunction against the Department of Agriculture and Consumer Services and the Department of Health and Rehabilitative Services. The case is still pending.

In conclusion, we are most appreciative of the interest of your committee and will be pleased to respond to any questions you or any members may have.

STATE OF FLORIDA **FLORIDA DEPARTMENT OF AGRICULTURE & CONSUMER SERVICES**

DOYLE CONNER COMMISSIONER * 3125 CONNER BLVD. TALLAHASSEE 32301

February 21, 1984

Committee on Environment
and Public Works
United States Senate
Room SD-416
Dirksen Senate Office Building
Washington, D.C. 20510

Attention: Ron Outen

Dear Mr. Outen:

As requested by Senator Durenberger in his letter of February 7, on the attached pages I have answered Senator Abdnor's questions as a follow-up to the EDB hearing on January 27, 1984.

Sincerely,

C. H. Van Middelem

C. H. Van Middelem
State Chemist
DIVISION OF CHEMISTRY

CVM:bc

cc: Senator Dave Durenberger
Senator Max Baucus

Attachments

QUESTIONS SUBMITTED ON BEHALF OF SENATOR ABDNOR

Question Number 1:

EPA left me with the impression that all citrus is treated with EDB. It is my understanding, however, that the only states receiving EDB treated fruits are those states which actually require treatment -- California, Arizona, Texas -- and the rest of the country does not receive EDB treated fruit. Is this the case?

Answer:

The following states require citrus fruit shipped from Florida be fumigated: California, Texas, Arizona and Hawaii. At the present time, only fruit shipped to Hawaii is fumigated with ethylene dibromide. Currently Florida fruit shipped to California, Texas and Arizona is fumigated with methyl bromide. California will also accept Florida fruit from certified fly free areas and fruit subjected to appropriate prior cold treatment.

Florida citrus fruit sent to all other states in the U.S. is not fumigated. Moreover, Florida citrus juice products processed from Florida fruit have not received any fumigation treatment.

QUESTIONS SUBMITTED ON BEHALF OF SENATOR ABDNOR

Question Number 2:

I have been advised that much of the concern in Florida is due to the possible threat of groundwater contamination. What precautions did you take at the state level to ensure protection of your unusually high water table?

Answer:

Ethylene dibromide has been recommended and widely used as a soil fumigant throughout the U.S. for decades. It was not discovered until very recently that EDB applied into the soil was not completely volatilizing and dissociating into relatively harmless inorganic bromides. Moreover, for the past 28 years, the federal regulatory agencies have established numerous official tolerances for inorganic bromides in agricultural commodities produced in EDB-treated soils.

Beginning in July 1983, after news of recent findings of trace quantities of EDB in California groundwater, drinking water samples were drawn in Central and West Florida and analyzed by the Florida Department of Agriculture and Consumer Services. Following the discovery of various trace quantities of parent EDB residues in some drinking water samples, Commissioner of Agriculture Doyle Conner declared a 60-day suspension on the use of EDB as a soil fumigant in Florida effective September 16, 1983. On October 7, 1983 Commissioner Conner permanently banned the use of EDB as a soil fumigant in Florida. This action prohibited the sale, distribution and use of EDB, even those quantities already in the hands of growers. This was more stringent action than EPA's emergency suspension which forbids only the sale and distribution of this soil fumigant.

STATEMENT
OF
THE FOOD & ALLIED SERVICE TRADES DEPARTMENT, AFL-CIO
REGARDING
THE REGULATION OF ETHYLENE DIBROMIDE
BEFORE
THE SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
OF THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U.S. SENATE

THE HONORABLE DAVID DURENBERGER, CHAIRMAN

JANUARY 27, 1984

I am Deborah Berkowitz, Director of Safety and Health for the Food and Allied Service Trades Department, AFL-CIO. This Department represents 45,000 grain elevator and mill workers throughout the United States. Our members work in grain elevators of all sizes, flour mills, feed mills, corn mills and soy mills. We appreciate this opportunity to discuss with you our experience with the regulation—or non-regulation of the toxic pesticide ethylene dibromide, and the serious consequences that have resulted from this inaction. We are both alarmed and disturbed at the regulatory foot dragging that has occurred around EDB by the agencies in charge of protecting the public from such poisons, and I hope our experience will never be repeated.

The grain elevator and mill workers we represent are true guinea pigs of the use of EDB in the food industry. They are like the canaries that miners brought down into the mines to test for deadly gas. For they are the people that, by law, must grade the grain by sticking their noses into samples of fumigated grain to smell for mold; they are the workers who have no right to receive any training when they fumigate grain and equipment with EDB; and they are the mill workers who can smell EDB for days in their workplaces following machinery fumigation—though the odor threshhold for EDB is estimated to be 100 to 200 times higher than the recommended safe levels. The experience of our membership with ethylene dibromide leads us to believe that from 1/2 to 3/4 of this nation's 250,000 grain elevator and mill workers may have been exposed to dangerous levels of this chemical. Despite years of our pleas for safer practices and fumigants in this industry, despite years of giving testimony about unsafe conditions, despite the availability of substitutes, and despite the growing list of EDB victims in the workplace, neither the government nor the industry moved to take action. And despite mounting evidence that deadly exposures may not end with workers—but are passed on to consumers in grain and citrus products -the regulators still remained silent.

I implore this Subcommittee not to let the problems of pesticide regulation fade from your memory when and if EDB has finally been controlled, but to begin to take steps to assure that the process of protecting the public from poisons will never again become victim to government malfeasance. Our laws governing the use of pesticides may indeed be a serious culprit, and may need reworking—but the last three years of complete regulatory silence despite mounting evidence of danger, must be held accountable.

I have here a chronological history of the inaction by regulatory authorities on EDB that I would like to submit to the record as Appendix A to our statement. This outline begins with the 1974 National Cancer Institute Memorandum of Alert describing the preliminary findings of EDB's carcinogenic activity in rats. It then traces this history to the 1975 petition to the EPA by the Environmental Defense Fund to take suspension action; to the 1979 and 1980 government studies showing EDB to cause cancer in rats and mice through inhalation at legally allowable limits for humans; to the 1981 EPA postion document claiming that immediate cancellation action on EDB's use as a pesticide on grain and milling machinery is warranted because "the presumption for oncogenicity, mutagenicity and reproductive disorders have not been rebutted... The Agency has determined that the risks to human health of certain uses of EDB are greater than the social, economic and environmental benefits of these uses and that risk reduction measures cannot reduce the risks to an acceptable level...;" to the agency's own scientist's statements that EDB is the most "potent, carcinogenic substance used as a pesticide today;" to the 3 year halt in all protective regulatory activity by OSHA, USDA, and the EPA—a silence that needlessly and irresponsibly left EDB on the market—despite meetings with these agencies that both regulations and a tolerance levels would be forthcoming; to the inadequate, loope hole ridden cancellation order meted out this fall by EPA that has already become victim to interagency squabbling - as it has been challenged by the Department of Agriculture.

What we are dealing with here is a system that needlessly left a chemical on the market—a chemical with available and cheaper substitutes—a chemical that may be the most carcinogenic substance ever tested by the National Cancer Institute. Internal squabbling within the Administration and the hand of political expedience appear to be the primary forces behind why the public was left unprotected. A closer look at our experience within the grain and flour industry should shed some light on this tortured regulatory history of EDB.

EDB is used directly on stored grain as a fumigant to kill grain pests. It is a minor ingredient in liquid fumigants used for this purpose, usually comprising from 1-4% of the ingredients. Most EDB containing grain fumigants are usually 80% carbon tetrachloride and 20% a witches brew of pest killers—of which a small percentage may be EDB. The government estimates that 243,000 gallons of the 3 million gallons of liquid fumigants applied to grain are EDB. Grain fumigants containing EDB are by no means the only fumigants used in this industry. In fact EDB is used mostly by small country elevators on grain that is stored for relatively long periods of time. The government estimate's that from from 11-40% of country and small inland elevators fumigate between 2.8 and 4.2 percent of the total grain handled in these elevators. In Nebraska, for example, a large grain state, only 10.7% of the elevators use EDB containing pesticides on grain.*

Grain worker exposure occurs when they handle grain that has been previously fumigated in a small elevators. This grain is fumigated by the county elevator prior to shipment by rail or truck to the larger elevator or mills. These pesticides, many of which contain EDB, rarely dissipate by the time the grain arrives at the shipping destination, which may be partially intentional, since fumigants can disguise the musty odor of grain which indicates infestation by pests—and would result in a poorer price for the grain. In addition, though many states have laws which do not allow fumigation below a certain temperature, the fumigant is frequently applied in cold temperatures that prevent the gas from dissipating. Because the trucks and railcars carrying this treated grain are not placarded with warning signs—unsuspecting grain workers at the receiving plants are often overexposed to these dangerous pesticides. Once the load of grain arrives at the elevator, all workers, from the inspector who must stick his nose into a sample of grain to sniff for mold, to the unloaders, can be exposed to the pesticide. A General Accounting Office report, published in 1980, called attention to the problem of grain worker overexposure to pesticides, when it said: "Despite many years of using fumigants as a means to rid grain and grain products of insect pests, and despite the involvement of many governmental agencies in various facets of this activity, workers continue to be exposed to potentially unsafe fumigant levels."

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*Centaur Associates, under contract by OSHA (see page 6)

In addition, government studies for the Occupational Safety and Health Administration by Centaur Associates document that EDB containing fumigants are also used in grain elevators to "treat" arriving grain as it is being moved into the elevator. Thus liquid fumigant is poured onto the grain as it enters the storage facility - exposing all employees to toxic levels. This method of applying grain was called "inappropriate and unsafe" by the formulators of EDB; but is commonly used in the industry. This is because the EPA label bearing the law on applying EDB essentially sets no guidelines: There is no mention of the carcinogenic or reproductive effect of EDB, nor of the slow dissipation properties of EDB. This is unlike many other toxic pesticides- which have strict requirements.

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*USDA Grain Marketting Research Center, Manhatten, Kansas

Back in 1975, our members first became alerted to the dangers of EDB's use to our workers and alerted the USDA, EPA AND OSHA to unsafe practices. If the workers could smell the EDB in the grain - the flip side of this hazard was that EDB was in the grain and was being passed on to the consumer. But no action by regulatory agencies was forthcoming.

There is no reason to continue allowing the use of EDB containing grain fumigants on the market. There are well used substitutes available such as, carbon tetrachloride based products without EDB and a pellet type fumigant called phostoxin. These substitutes are not only well used in the industry, but are cheaper. EPA has estimated that a cancellation of EDB's use on grain would actually save money. I am alarmed, and somewhat dismayed to hear that certain sectors of the industry claim that 40% of our grain has been fumigated with EDB. First, this flies in the face of repeated USDA statements to our membership that only between 7-20% of grain in this country is fumigated—and therefore, we have no need to worry about pesticide exposure of our membership. And second, all government estimates show that less than 4 percent of the grain that is fumigated has been treated with EDB. This 40% figure appears to be an attempt to paralyze the government into complete inaction by painting a tremendously extensive problem.

With all the public outcry over EDB in food products though, it is still being used on grain. Our workers still report finding cans of EDB containing fumigant in trucks arriving at their elevators. Given the new residue data found in consumer products, the lack of safeguards in using EDB and the availability of cheaper substitutes—an emergency suspension of the use of EDB on grain must be ordered. (The cancellation order already proposed by the agency will not protect the public for it has been challenged by pesticide formulators—allowing their EDB containing products to remain on the market. And though the grain industry has not challenged the order—the USDA has challenged the order, saying the grain industry needs these fumigants. This raises serious questions in our mind about USDA's role.)

The most widespread use of EDB in the food industry is as a machinery or "spot" fumigant in flour and feed mills. Unlike the EDB based fumigants applied to grain, the EDB products used on equipment to control insect infestation are 50-80% EDB. The government estimates that 465,000 pounds of EDB are used annually in this manner. According to a government study, each mill used EDB an average 10.38 times per year, though our experience has been that mills will fumigate every two weeks.* EDB was used so heavily in this industry because it volatilizes slowly, allowing EDB vapors to continually evolve from the fumigant (a process known as off-gassing) and replace the fumigant gas lost from relatively leaky flour mills . In addition, EDB is cheap to use because it is relatively unregulated. Unlike the substitutes for EDB — EPA has never set safe practices for the application of this fumigant, thus allowing mills to use it without shutting down for adequate periods of time.

When applying EDB spot fumigants to flour milling, feed mill or cereal mill equipment, the equipment is run until it is empty as possible, leaving only small quantities of the grain product trapped in the machinery. (Grain products do remain, as was brought out in testimony by our members before the Congress last fall, see Appendix B.) The EDB is then applied through an applicator gun into every piece of equipment in the mill. The workers applying the fumigant are not required to receive any training in the hazards of EDB or how to apply it. The only laws on this account are that they must work under a certified applicator—who is usually the plant manager and who usually does not supervise the application. The unregulated application of EDB has claimed many victims. I submit to the record, Appendix B, the testimony of one of our members, Mr. Dave Smith, who volunteered to do spot fumigating to make some extra money. He was given an applicator gun, not told what he was fumigating with, and sent off to apply EDB to his elevator. The applicator gun that David was handed was leaking and Dave got some EDB on his hands and trousers. Within one hour he began to have severe headaches. Within 2 hours his body had gone completely numb and while in the hospital his heart beat was down to 29 beats a minute. And nobody at the plant could tell the hospital what Dave was working with, because nobody was told it was EDB.

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*Analysis of Four Industry Segments which would be affected by proposed EDB Standard," prepared for OSHA, Oct 13, 1983, Centaur Associates Inc.

From surveys we have done of our membership, we found that anywhere from 10 to 17 hours after this fumigation is done, the mill is reopened—usually about one hour prior to starting time. Windows are opened and an attempt is made to aerate the mill. However, when starting time arrives at 7:00 a.m.—the time when the first shift arrives at the plant, the smell of EDB hangs thick in the air. I read to you from the testimony of the President of one of our local unions given before the House Subcommittee on Labor Standards last fall: "I have been fumigating this mill for 7 and one-half years now and I have always been able smell the EDB for almost the full day upon reentering the mill. When we start moving the grain and flour through the mill and in the bins that have been fumigated and through the sifters and grinders, the product picks up the undissipated EDB—and the left-over product soaked with EDB — and even the workers who bag the final product at the end of the line, complain they can smell the EDB!

None of the workers are given protective equipment--nor is there any word about the dangers of this substance. With EDB, I learned that once you smell it, you are exposed to at least 10 ppm--and maybe even over 20 ppm. Given the low levels that the federal government is now recommending as safe (100 pp/billion)--grain millers are exposed to extremely toxic levels of EDB--almost 100 times the safe levels. Workers in my plant always complain to the company of headaches, nose irritation, and burning eyes that day following fumigation. My plant has never monitored for levels of EDB in the plant."

This experience is repeated in hundreds of flour mills and feed mills across the country. We have even received testimony from workers where the conveyor in a feed mill will be fumigated while workers are still on the second floor grinding areas! And we have testimony of workers becoming ill from EDB--the symptoms ranging from headaches to near death experiences like that of David Smith. Last Tuesday, I heard an industry scientist on McNeil-Lehrer Show that workers are not getting sick from EDB so consumers should not become alarmed. This man has obviously never talked to a grain mill worker.

The label on the EDB fumigant — which carries the EPA regulations — is partially to blame for this callous use of EDB that leaves residue on the equipment that is subsequently absorbed by new product moving through the equipment and shipped off to the consumer. The label suggests that 24-hours should go by before opening and restarting a mill following fumigation. But there are no hard and fast regulations — and the experience of my membership suggests that only 10-15 hours of waiting is allowed. I am not convinced though, that even 24-hours would assure that the EDB has dissipated. A government study by Centaur Associates suggests 41-hours, plus ventilation prior to start-up would reduce EDB levels to below 130 ppb — but not eliminate the EDB from the mill.

For years both the industry and government maintained there were no suitable substitutes to EDB in the industry. The real tragedy here is there are safer and readily available substitutes for EDB in this industry; substitutes that have been in use in at least one-fourth of the plants we represent. And as of this September, I assume the majority of the milling industry has switched to these substitutes. For, following testimony by our members before Congress last fall about the extent of worker exposure to EDB, and in the shadow of sending orders by EPA for cancellation, the major milling companies have all publicly stated that they have suspended use.

The substitutes will probably be a combination of methy bromide, malathion and pyrethrins. A few of our mills in Kansas are experimenting with heat treatments.

EPA estimates that spot fumigation contributes significant residues of EDB to flour. In addition, EDB is used in the feed industry, where EDB contaminated product is fed to cattle, sheep, chickens, etc. With the availability of substitutes and the data on residues in wheat, flour, meat and milk, we were deeply disturbed by EPA's failure to issue an emergency suspension of the use of EDB on milling equipment. We were equally alarmed to learn that they were not aware of the milling industry's suspension of the use of EDB, or of the use of substitutes in the industry, until after they issued the cancellation order. Because the order has been challenged by two formulators of EDB spot fumigants — it is still on the market and may still be in use at smaller mills.

Mr. Chairman, with other substitutes for EDB being used in this industry, we urge you to assure that EPA set strict guidelines on their use as a machine fumigant. With the new reliance of methyl bromide in the industry, we are especially concerned about this chemical because of its acute toxicity. Currently EPA regulations require that mills be shut for 24-hours following fumigation with Methyl bromide. Upon entry, many labels require the use of a 'halide leak detector' instrument to detect any methyl bromide left inthe atmosphere. However, this is a flame device — which is also not very accurate. Using a flame device in elevators and mills is dangerous due to the explosibility of grain dust. We hope EPA sets new regulations requiring other means of detection. (In addition, no long-term studies have been done on methyl bromide! Studies should be undertaken at once!)

We must assure that EDB no longer contaminates the food on our shelves — nor poses a hazard to our grain elevator and mill workers. In addition to setting tolerance residue levels in food — we must stop the needless contamination of the food in the first place. EPA has told us since September that they were gathering information to see if there indeed should be an emergency suspension of EDB use — but they have yet to conduct tests on their own or even set a tolerance level in food. After waiting six years for protection, it is easy to lose faith. And on top of this, the USDA's insidious efforts to keep EDB on the market makes the hope that the public's interest will eventually be served even more dubious. USDA has joined with other challengers of EPA's cancellation order to keep EDB on the market for its use on grain, milling equipment, and citrus. Though the grain and milling industry did not challenge the ruling — the USDA is! They have even held strategy meetings, reported about in the January 21st Washington Post, with all the challengers to plan how to best keep EDB on the market!

Mr. Chairman, regulatory foot dragging has needlessly left both consumers and workers unprotected from a market poison. For many years the EPA has shirked their responsibility to both workers and consumers. Let us not shirk this responsibility any longer. We must move swiftly ahead to protect the public. The cost of not moving — will only be a national tragedy.

EDB: A HISTORY OF INACTION

1974: National Cancer Institute issues a "Memorandum of Alert" describing a preliminary finding of EDB's carcinogenic activity in rats and mice (oral route).

1975: Environmental Defense Fund petitions EPA to investigate EDB and to take suspension or cancellation action.

NCI study shows EDB to be carcinogenic in both sexes of rats and mice.

1976: The National Institute for Occupational Safety and Health recommends that EDB be treated as a potential occupational carcinogen and recommends a safe workplace level at 130 ppb (200 times lower than current standard).

Studies show EDB to be mutagenic.

1977: EPA issues a Notice of Rebuttable Presumption Against Registration. EPA cites literatures identifying EDB as a carcinogen. Begins special review.

1979: NIOSH completes inhalation study that shows EDB to be animal carcinogen.

1979: DBCP, a chemical closely resembling EDB in make-up, use suspended by EPA.

1980: NCI completes inhalation study that shows EDB to be an animal carcinogen.

1980: EPA issues Position Document 2/3: Preliminary Notice of Determination Concluding the RPAR. The Federal Register Notice announcing availability of the Position Document states: "After reviewing all available information the Agency has concluded that the presumption for oncogenicity,mutagenicity and reproductive disorders have not been rebutted .... The Agency has determined that the risks to human health of certain uses of EDB are greater than the social, economic and environmental benefits of these uses and that risk reduction measures cannot reduce the risks to an acceptable level ... Aft-r evaluating the human health risks and the economic benefits the Agency has reached a preliminary decision to immediately cancel use of EDB on stored grain, flour mill machinery and felled logs; to cancel use of EDB for post-harvest fumigation of citrus and tropical fruits effective July 1, 1983; ... Residues in wheat and citrus are documented in this notice.

1980-
1983: The three year gap in further tests and action by the EPA on exposure of workers and public to EDB, though the agency's own scientists labelled EDB as "the most carcinogenic pesticide in use today."

Oct
1981: California issues an emergency temporary standard for limiting workers' exposure to EDB to 130 ppb. Milling industry claims to be exempt. USDA, EPA and OSHA met with industry and labor representatives over EDB's use on citrus: promise to set a tolerance level in food. (See attached memorandum.) Nothing is done, however.

Teamsters and AFL-CIO petition federal OSHA for a nationwide emergency standard on EDB. Federal OSHA denies petition.

Feb
1982: NIOSH urges OSHA to reevaluate its position in not setting an emergency standard. In a letter to OSHA Administrator Thorne G. Auchter, J. Donald Millar, Director of NIOSH recommended that Auchter reevaluate his position, "in view of the rapidly growing scientific evidence for the carcinogenic and mutagenic potential of EDB and its effect on reproduction."

Sep
1983: House Subcommittee on Labor Standards holds hearings on worker exposure to EDB. Representatives from American Federation of Grain Millers testify on worker exposure 100-200 times safe levels recommended by NIOSH and CAL-OSHA. Contrary to EPA assertion that milling industry is dependent on EDB, workers testify it is not used in 1/4 of the industry.

Two weeks after hearings, all major milling concerns voluntarily suspend usage of EDB as a machinery fumigant.

OSHA publishes an EDB proposal regulating the chemical as a carcinogen. (This is 2 years after they denied petition.)

Sep
1983: EPA orders the immediate suspension of EDB as a soil fumigant for agricultural crops. A cancellation order for EDB's use on grain and/or grain milling machinery was issued and a phased-in cancellation of EDB's use on citrus was announced.

Oct
1983: The State of Florida, major citrus growers and the manufacturers of EDB fumigant for use on citrus challenge EPA's orders. Eight manufacturers of EDB based pesticides for milling machinery and stored grain also challenge ruling. No grain industry users issue challenge.

For these users and manufacturers, the cancellation does not take effect. Thus, mills may use the fumigants made by companies listed on the attached. Grain elevator workers report grain is still be fumigated with EDB.

Dec
1983: USDA joins challenge to EPA's cancellation order of uses of EDB on grain, milling equipment and citrus. Though the milling industry has suspended its use of EDB as a spot fumigant and though the grain storage industry has not challenged order because there are cheaper alternatives to EDB (phostoxin, weevilcide), USDA argues these uses are necessary.

Dec
1983: EPA first sets up model mill in Kansas to conduct tests on residues in flour.

Jan 5, 6
1984: USDA convenes a closed door meeting at the American Farm Bureau Association to discuss "strategy" on fighting cancellation order. All challengers to EPA, except the two unions, are invited. The unions support cancellation order. (See attached Washington Post article.)

Jan
1984: EPA meets with industry, labor unions (in separate meetings) to discuss potential action on emergency suspension and setting a tolerance level. But industry spokespersons in "Produce News" state: "From other comments the EPA administrator made, however, Keeney (United Fresh Fruit and Vegetable) surmised that a citrus suspension was only a remote possibility." (See attached)

Jan
1984: Florida and Texas, both users of EDB on citrus, test grain products for EDB. Florida recalls 77 grain based products but continues to use EDB on all fruit shipped to California and other citrus producing states. Texas finds EDB residues, confirms Florida's findings. California bans importation of citrus fumigated with EDB. California suspends all use of EDB in state.

ACTION NEEDED

- EPA should issue an immediate emergency suspension of the use of EDB on grain and milling machinery to prevent entry of EDB into the marketplace. No further tests are necessary. Substitutes--that are even cheaper--are available.

- EPA must set a tolerance level in food.

- EPA must issue an emergency suspension of EDB's use on citrus. Encourage the development of safe alternatives.

Appendix B

STATEMENT
OF
THE AMERICAN FEDERATION OF GRAIN MILLERS
REGARDING
THE REGULATION OF ETHYLENE DIBROMIDE (EDB)

BEFORE
THE SUBCOMMITTEE ON LABOR STANDARDS
OF THE
COMMITTEE ON EDUCATION AND LABOR
U. S. HOUSE OF REPRESENTATIVES
THE HONORABLE GEORGE MILLER, CHAIRMAN
SEPTEMBER 13, 1983

I am Don Bowman, President of American Federation of Grain Millers Local 71, Vallejo, California. The American Federation of Grain Millers represents over 35,000 grain elevator and mill workers throughout the United States. Our members work in export elevators, inland terminals, feed mills, corn mills, flour mills and sugar mills. We appreciate this opportunity to discuss with you the serious consequences of the grain industries dependence on the use of the pesticide, ethylene dibromide. We sincerely thank the Chairman for convening these hearings on this important issue.

Ethylene dibromide is an ingredient used in over 100 different registered pesticides. For the record, I would like to submit the names of the twenty most commonly used of these pesticides in the grain and flour industry. The concentration of ethylene dibromide within these pesticides varies according to its use, from 1% EDB--up to 70% EDB. Those pesticides containing the largest amount of EDB are used as a spot or machinery fumigant--a chemical brew which is applied to milling and storage equipment to prevent infestation. EPA estimates that 465,000 pounds of EDB are used in this manner. The other use of ethylene dibromide is as a grain fumigant, where its is applied to the grain being stored in an elevator to ward off infestation by pests.

I come here to tell you that a combination of regulatory foot dragging and a needless dependence on this deadly pesticide may have brought about a new set of victims of industrial toxins--the American grain worker. The experience of our membership with ethylene dibromide leads us to believe from 1/2 to 3/4 of this nation's 250,000 grain elevator and mill workers are at risk. I want to share with the Committee the experience of our membership--experiences which underscore the tragic consequences that result from failing to act in a prudent and responsive manner to poisons in the workplace.

I work in a flour mill, and for the past seven and half years, I have fumigated this mill using an ethylene dibromide based pesticide. Since my plant consists of 8 floors--filled with 94 elevator legs that transport the grain and flour through the mill, grinders to grind the grain, huge sifters that sift the grain and dust collection equipment, six people are used to spot fumigate the mill. Using 60 gallons of the fumigant, the ethylene dibromide is shot by gun into over 800 hundred different pieces of equipment. Only in empty flour bins, do we use 4 ounce cans and pour the contents out.

The mill is usually fumigated with EDB once every two weeks. After everyone leaves work on the date of fumigation--usually on Sunday, the mill is closed down and all windows are closed. Because of the hundreds of individual pieces of machinery that must be shot with the EDB, this process usually takes from 2-3 hours. Anywhere from 13 to 19 hours after this fumigation is done, the mill is reopened--usually about one hour prior to starting time. Windows are opened and an attempt is made to aerate the mill. However, when starting time arrives at 7:00

a.m.--the time when the first shift arrives at the plant, the smell of EDB hangs thick in the air. I have been fumigating this mill for 7 and one-half years now--and I have always been able to smell the EDB for almost the full day upon reentering the mill. When we start moving the grain and flour through the mill and into the bins that have been fumigated and through the sifters and grinders--the product picks up the undissipated EDB--and even the workers who bag the final product at the end of the line, complain they can smell the EDB! None of the workers are given protective equipment--nor is there any word about the dangers of this substance. The label on the fumigant suggests that you should wait 24 hours before opening and restarting the mill, following fumigation. We don't wait that long--and even if we did, I am not convinced that all the EDB would be gone when we arrived. Though workers in my plant continue to complain to the company of headaches, noise and eyes burning that day following fumigation--my plant has never monitored for levels of EDB in the air.

In fact, before I attended a seminar sponsored by my union on the dangers of pesticides, I did not know there was much reason to be concerned. Some of the pesticides we use in our plant, have an odor that is a warning that you are about to be overexposed (for example, phostoxin). But with EDB, I learned that once you smell it, you are exposed to at least 10 ppm--and maybe even over 20 ppm. Given the low levels that the government scientist recommend as safe (130 pp/billion)--and the low level passed by the

California OSHA--my members, who can smell the EDB, are consistently exposed to extremely toxic levels of EDB (almost 100 times the safe levels).

Mr. Chairman, the experience of my members is repeated in hundred of elevators and mills across this country. At Local 49 of the American Federation of Grain Millers in Iowa Falls, they also use ethylene dibromide as a spot fumigant on their conveying system. The system is shut down on Saturday nights, and at 7 on Sunday morning the conveyor is fumigated in approximately 20 locations, using a funnel and pouring the liquid into the different locations. Two workers--neither of which are provided with protective equipment--are present on the second floor of the mill--in the grinding areas, while the conveyor is being fumigated. These people get a strong dose of this EDB--and complain of nausea and headaches up to 10 hours after the fumigation is initiated. Again, there is no monitoring of levels, no medical checking, no warning about unsafe chemicals.

In a flour mill in Minneapolis, in AFGM Local 1, they use EDB as a spot fumigant once every two weeks. According to reports from the workers, they smell the EDB following start up after fumigation. It is so bad on the sixth floor of the mill that people gag and complain of upset stomach and of not feeling well. Sometimes, they even spot fumigate a piece of machinery while people are working. The workers are not provided with respiratory protection--and ventillation is not adequate to assure that safe levels are maintained.

At public hearings held by the Occupational Safety and Health Administration three and half years ago on the health hazards in grain elevators and mills, our union presented over 30 witnesses to testify about the problems with fumigants. The President of our Local 55 in Denver described the situation at his plant. He spoke of how they fumigated with ethylene dibromide once a month on weekends. Upon reentering the plant on Monday mornings, the workers detected a very strong odor. During one particular fumigation, he notified the foreman that a few workers were becoming nauseous, having a burning sensation in their eyes and lungs. The forman simply responded, "Open the door. You guys will be okay. Don't worry about it."

Despite repeated proclamations by the industry that only the fumigator is exposed to ethylene dibromide, it is clear that all grain mill workers may be at risk. These grain workers are not told of the risk, they are not warned of the dangers--in fact, you just come to expect that feeling sick the day after fumigation is part of the job.

The real tragedy is that there are safer and readily available substitutes for EDB in our industry, substitutes that are used in at least 1/4 of the plants we represent. In fact, a few hours away from my mill, in San Leandro, our local union represents a mill that does not use EDB. Instead they use a combination of malathion and pyrethrins--two of the safer pesticides on the market today. And in a few mills in Kansas

City, they have stopped using pesticides altogether for machinery disinfecting--they have begun to use heat.

In addition to its use as a spot fumigant, ethylene dibromide is used directly on the grain to prevent infestation. In this capacity, only a small percentage of the pesticide is EDB. These pesticides are usually applied to the grain in small country elevators prior to the grain's shipment by rail or truck to a larger elevator or mill. These pesticides, many of which contain EDB, rarely dissipate by the time the grain arrives at the shipping destination, which may be partially intentional, since fumigants can disguise the musty odor of grain which indicates infestation by pests--and would result in a poorer price for the grain. Because the trucks and railcars carrying this treated grain are not placarded with warning signs--unsuspecting grain workers at the receiving plants are often overexposed to these dangerous pesticides. Once the load of grain arrives at the elevator, all workers, from the inspector who must stick his nose into a sample of grain to sniff for mold, to the unloaders, can be exposed to the pesticide. A General Accounting Office report, published in 1980, called attention to the problem of grain worker overexposure to pesticides, when it said: "Despite many years of using fumigants as a means to rid grain and grain products of insect pests, and despite the involvement of many governmental agencies in various facets of this activity, workers continue to be exposed to potentially unsafe fumigant levels."

Mr. Chairman, in 1980, the Federal government's Environmental Protection Agency announced in the Federal Register that they had decided that the risks to human health posed by EDB's use on grain and its use as a spot fumigant in the milling industry are "greater than the social, economic, and environmental benefits of these uses, and that risk reduction measures cannot reduce the risk to an acceptable level. Accordingly, the Agency proposed to initiate action immediately to cancel or deny registration for all such uses." It's been three years since this statement was made, three years of inaction.

And also three years ago, our union went before the Occupational Safety and Health Administration to ask for better protection from grain pesticides. We welcome the announcement of a proposed Federal OSHA standard, but if our experience with the grain safety standard is any indication of the current regulatory procedures, we are still in for a long haul as OMB takes a look at this standard.

In my state of California, the Department of Food and Agriculture cancelled EDB's use in our industry as of August 15. However, all supplies of EDB currently on hand may be used up, and, of course, my company has a good year's supply of EDB left. In California, we also have a strong CAL-OSHA standard--but because of the lack of a Federal counterpart--the industry is not complying with the standard in the proper spirit.

Despite the numerous studies indicating EDB to be a potent carcinogen, despite evidence that it is a reproductive hazard--the current label on EDB containing pesticides contains none of this information. And the members of my union, the grain elevator and mill workers, are provided no education or training on the hazards of EDB. We are provided with no medical screening, no monitoring of levels, and little protection. In the quest to prevent the infestation and subsequent destruction of the grain and flour by pests--worker safety has taken a back seat.

For many years the grain industry has shirked their responsibility to the workers in this area. Let us not shirk this responsibility any longer. We must move swiftly ahead to protect workers. The costs of not moving--will only be a national tragedy.

I am Dave Smith, a member of local 1 of the American Federation of Grain Millers. I work in a elevator and flour mill in Minneapolis as a shoveller.

I have heard today that exposure to EDB can cause cancer and other problems that may not show up for years and years. What my future holds, I do not know. But, I do know that I am one of the many workers who was exposed to a small amount of edb that almost cost me my life.

Two years ago, I signed up to do spot fumigating, to make some extra money. The spot fumigating is done once or twice a month on a Saturday and Sunday, and they use regular mill personnel as helpers, along with the licensed fumigators. On the Saturday morning I was signed up to work, I was given a gas mask, and an applicator. We were fumigating with WACO 50/50 which is 50% ethylene dibromide. I was given an applicator that was not working properly, and in the course of the fumigating I got some of the liquid on my hands. We had been only told that if we get it on our skin to wash it off. So about 10 minutes later, when I had a chance, I washed it off. During the next forty-five minutes, I again spilled some on my hands and on my trousers. After 5 minutes I washed my hands but not my trousers - I didn't think that there could be any problem.

Within 45 minutes, I began to get a severe headache. I thought it was my gas mask that was too tight. So I loosened the gas mask and kept working. The headache got worse, and I started getting dizzy and my body felt very rubbery. My knees felt like buckling in. It was as if my whole body was starting to go numb. I was up on the sixth floor and in order to get down to the bottom, I had to take the manlift. I was so dizzy that I could hardly hang on to the lift. When I did get to the bottom, my legs were so numb that I could not walk - I crawled in to the locker room. A couple of the fumigators were taking a break and they helped me into the room. It was then became violently ill - I threw up, I alternated between feeling hot, cold, and I just felt terribly sick. One of the guys took me to the hospital and as I walked through the door, I just collapsed. My body had gone completely numb. I was in the hospital for five days - I was hooked up to an IV, and was given oxygen. I was put in the Intensive Care unit -where they monitored my heart and lungs. They said that at one point my heart beat was down to 29 beats a minutes. A normal heart beat, during waking hours is 72 beats a minute. The doctors didn't know what the problem was. But they finally told me that I had bromide poisoning and that it was touch and go as to whether I would make it or not.

This was my experience with EDB - I haven't signed up to fumigate since, and I won't ever again - it's not worth the risk.

I'm not the only person in my mill, though that may be at risk.

Up until May of this year, we were spot fumigating while the mill was running and workers were on the job. Those people doing the fumigating would take about a quart of pesticide - the mixture contained 59% EDB - and dump it into empty bins in the mill, and also in the packing and loading area in the elevator. You could smell the EDB in the air right away - and I know other workers complained about getting headaches. I know that whenever they did this, about once or twice a week, I would leave the area - I didn't want to be any where near the stuff.

I know of one other instance where a guy was fumigating and he spilled some EDB on his feet, and on his genital area - both his feet and his testicles swelled up.

I believe that there has got to be a safer substance to use than EDB.

I almost died from being exposed to it. At least workers should be told how dangerous it really is. I hope my testimony has been of help to you here today.

Thank you.

STATEMENT
OF
THE INTERNATIONAL BROTHERHOOD OF TEAMSTERS
REGARDING
THE REGULATION OF ETHYLENE DIBROMIDE (EDB)

BEFORE

THE SUBCOMMITTEE ON TOXIC SUBSTANCES

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

U. S. SENATE

THE HONORABLE DAVE DURENBERGER, CHAIRMAN

JANUARY 27, 1984

Good morning. My name is Suzanne Kossan, and I am the Industrial Hygienist for the International Brotherhood of Teamsters. We appreciate the opportunity to appear here today and wish to express our gratitude to you, Mr. Chairman, for your interest in the regulation of toxic substances like ethylene dibromide (EDB).

As the representative of tens of thousands of workers employed in the transportation and warehousing of EDB fumigated citrus and tropical fruits and in grain milling and handling, we have a vital interest in the regulation of the toxic pesticide EDB. We are here today to express our deep concern over what we believe is EPA's failure to effectively regulate EDB and to highlight the events which we feel underscore the agency's unwarranted and unnecessary delay tactics.

The toxicity of EDB began to reveal itself as early as 1965. At that time, investigators found that adverse reproductive effects developed in test animals challenged with EDB. The peril of EDB, however, accelerated in 1974 when a study by the National Cancer Institute (NCI) revealed that EDB caused cancer in the forestomachs of mice and tumors in rats. In light of the NCI study, the Environmental Defense Fund petitioned EPA to ban EDB in 1975. EPA denied the petition. Instead, EPA announced a formal review of the risks and benefits of EDB and solicited public comments and additional data.

While EPA collected information, new animal studies further implicated EDB as a carcinogen, mutagen and reproductive toxin. The chemical was shown to damage the sperm and testicles of animals such as bulls, rams and male rats. A 1980 NIOSH study revealed that EDB caused tumors in test animals when inhaled. A second NCI study, this time an EDB inhalation study, showed tumor development in test animals of various species, at various doses, in both males and females, and at multiple anatomic sites. It would be difficult to get more damning evidence of cancer causing ability without waiting for the unthinkable: a human body count. Is it any wonder that our members are afraid to do work that exposes them to EDB?

In light of this incriminating scientific evidence, EPA proposed, in 1980, an immediate ban of EDB uses on soil and grain and a phase out on citrus. At the time EPA scientists stated that the "calculated risks from using EDB were among the highest risks the agency has ever confronted". In 1980, we believed we would see some immediate regulation of EDB. Instead, we saw unnecessary and unwarranted delays.

While EPA sat on their proposal, firm evidence of dietary exposure to EDB was published. By October, 1981, FDA and EPA were well aware of significant EDB residues in foodstuffs. In fact, FDA results transmitted to EPA showed that 98% of fruit tested had detectable levels of EDB. Of this 98%, 56% were levels of less than 250 ppb while 10% exceeded a level of 3000 ppb. [1]In addition, EPA was informed, through an A.D. Little Study, that minor changes in fumigation practices would reduce EDB residuals and exposure levels. [2]On December 22, 1981, EPA officials informed us that they would set an EDB residue level within a few months. A few months became 2 years and we still have no effective regulation of EDB.

What took place in the agency from December 1981 to 1983? In our belief, NOTHING. No new information on EDB risks and benefits was generated by EPA during these years nor was the agency busy promoting alternatives. By December 1981, a complete record justifying the need for regulation of EDB had been made, but a decision had been delayed - delayed by what we believe are special interest politics.

Special interest politics underlie resistance efforts to EDB regulation. USDA has spearheaded resistance efforts by coordinating strategy sessions with affected industry groups. We were invited to one such strategy session but were later disinvited when it became clear that we favored banning the chemical. We are dismayed that industry and USDA have chosen to develop strategies to defend the use of EDB rather than perfect safe alternatives.

When EPA finally made an effort to regulate EDB, on September 1, 1983, it was a weak effort. The agency banned EDB as a soil fumigant but merely ordered its cancellation for use on grain and citrus. Industry groups immediately challenged the cancellation orders. As a result, the orders have been stayed and EDB has continued to be used on grain and citrus. We believe EPA's September 1, 1983, action fell far short of what is needed to regulate the deadly chemical.

We believe what is needed is an emergency suspension of all remaining uses of EDB. Alternatives to EDB are available and are in use. Major grain companies have voluntarily suspended the use of EDB on grain. In response to California's refusal to accept EDB-treated citrus into the state, Florida and Texas have agreed to fumigate citrus with other pesticides. Irradiation will be used commercially on papayas, mangoes and other tropical fruits in Hawaii as a result of a joint venture between Radiation Technology, Inc., and Hawaiian tropical fruit interests. Irradiation is currently used on certain foods in 28 countries including Japan, the Netherlands, and Canada. Cold treatment, heat and low oxygen environments are other alternative technology possibilities. An EPA action to ban EDB will force the use of these technologies on a commercial scale and will reduce health risks to our members and all workers exposed to EDB.

In summary, over 6 years since EPA made the decision to evaluate the risks and benefits of EDB, there is still no effective regulation of EDB. Meanwhile, the EDB problem persists. Recent studies by California Department of Food and Agriculture show the EDB residue levels in citrus remain as high as 16,500 ppb in the peel and 1420 ppb in the pulp. [3]These residues continue to pose a dietary risk to american consumers and a health risks to workers when residues offgass in the environment. From 1977 to the present, EPA has been reluctant to reduce these risks and ban all uses of this deadly chemical. We believe that EPA, in not taking final action on EDB, has acted in direct conflict with the mandate given them by Congress.

On January 20, 1984, we met with Mr. William Ruckelshaus to discuss the regulation of EDB. We were informed that the agency would reach their decision on issuing an emergency suspension on EDB and setting a residue level for foodstuffs within the next 2 weeks. Indeed, we are encouraged that the agency is reconsidering their position on EDB. We hope that the EDB issue will not become a political football to be buried after the elections. We are seeking effective regulation of this deadly chemical by EPA and are looking toward Congress to assure that appropriate action is taken.

We appreciate your efforts Mr. Chairman and the efforts of this Subcommitte to oversee the resolution of the EDB problem.

REFERENCES

1. "Ethylene Dibromide in Citrus Fruits", Food and Drug Administration, October 27, 1981, communication to Joseph Panetta, USEPA.
2. "Ethylene Dibromide", A.D. Little, Inc., December, 1981.
3. "Citrus EDB Analysis", California Department of Food and Agriculture, January, 1984.

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Testimony of Ellen Haas
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before the
Toxic Substances and Environment Oversight Subcommittee
Committee on Environment and Public Works
January 27, 1984

EDB and the Consumer

Mr. Chairman, good morning. I am Ellen Haas, Executive Director of Public Voice for Food and Health, a nonprofit consumer research and advocacy organization focusing on food, nutrition and agriculture issues. One of our principal objectives is to ensure that national policy-makers adequately consider the consumer consequences of the health and economic policies they establish, and that programs in these areas reflect more than a one-sided attention to the needs and wishes of regulated industries. In our view, the case of EDB is a classic example of agency inattention to consumer and environmental hazards and prolonged use of a chemical pesticide which should not have been registered in the first place and which certainly should have been removed from the market long ago. In order to minimize further risk from this lethal chemical we believe it is imperative for the EPA to move quickly to cancel remaining uses and establish legal tolerances. And in order to minimize the potential for future EDB crises we believe the Congress must strengthen the statutes under which pesticides are approved and residues are regulated.

At the outset I must say that we are relieved that the EPA has published an emergency suspension order for the use of EDB as a soil fumigant. Accounting for the majority of the pesticidal use of the chemical, such use has been shown to result in the contamination of ground water in at least four states, and wells have been identified with up to 300 parts per billion EDB. In addition, this use could likely lead to the contamination of crops--a source of dietary exposure extending beyond that resulting from post-harvest fumigation of citrus products and grain.

Yet we are deeply disturbed that the agency has not moved to cancel other registrations on an emergency basis and especially that it has refused to set any tolerance levels for residues of the chemical on consumer food products.

EDB has enjoyed pesticidal use for approximately 30 years and for nearly two thirds of that time there has been at least a suspicion of health hazard about the chemical. As early as 1965 it was determined that EDB caused reproductive problems in laboratory animals, and less than ten years later the National Cancer Institute had identified the chemical as a likely carcinogen in a "Memorandum of Alert." In the late 70's a number of studies confirmed the powerful carcinogenic nature of EDB and in 1977 EPA issued a Notice of Rebuttable Presumption Against Registration. Through this process the sponsors of the pesticide were given the opportunity to present evidence supporting the continued use of EDB but by December, 1980 the EPA announced that the presumption of carcinogenicity and other hazards had not been rebutted and that "the risks to human health of certain uses of EDB are greater than the social, economic, and environmental benefits of these uses and that risk reduction measures cannot reduce the risks to an acceptable level." 45 Fed. Reg. 81516. The agency announced a number of steps to restrict the registration of EDB, but for nearly three years not one of these steps was actually taken.

By far and away; this three year hiatus is the most objectionable and troublesome element of the entire EDB regulatory process. Whether because agency staff was reduced or industry pressure exerted, it does not matter; the fact is the agency has allowed the public to be placed at significant risk of cancer and other diseases for an unnecessarily long period. We believe the risk has been great enough for long enough and that the time has arrived to rid the environment and the food supply of this lethal pesticide.

Mr. Chairman, we strongly believe that a number of steps must be taken to minimize the EDB contamination problem and expedite removal of the pesticide from the food supply. At the same time, however, we hope that this committee and the Congress generally will take the opportunity to consider needed changes in the statutes which are supposed to protect the public from such pesticide hazards.

With respect to EDB, we believe the EPA must issue an emergency suspension of the registration for use of the pesticide as a post-harvest fumigant of grains and citrus products and as a spot fumigant of grain milking machinery. For the grain uses, it is not at all clear why the EPA has not already taken action to cancel registration. In addition to the residues left in food from such uses, there is tremendous and unreasonable risk posed to workers who store, transport and test the quality of the grain. What is more, we are told that there are even effective alternatives to EDB in this usage which are cheaper to use than EDB.

With respect to citrus products, we believe it is equally important that the EPA act to immediately cancel fumigation registration. The EPA itself has estimated that worker exposure from the fumigation of citrus is likely to be the highest for any EDB use, and that workers in this area have "an extremely high increase in their risk of cancer." 48 Fed. Reg. 46240. What is more, the general public is posed considerable risk from this source of exposure; the EPA concludes that the general public may typically face significant increases in cancer risks from consumption of treated fruit. Id. Although inherently crude and unrefined, the risk assessment data of EPA indicates that "EDB in fresh citrus results in an increased lifetime risk of cancer of $2x10^{-5}$ in states which do not require fumigation" and higher in states, such as California, Arizona, New Mexico and Texas, which do require such treatment. Thus, by these rough calculations which may actually underestimate actual risk, the use of EDB on citrus may lead to at least two extra cancer victims per one hundred thousand persons exposed, or at least 4,400 additional lifetime risk of cancer of $2x10^{-5}$ in states which do not require fumigation" and higher in states, such as California, Arizona, New Mexico and Texas, which do require such treatment. Thus, by these rough calculations which may actually underestimate actual risk, the use of EDB on citrus may lead to at least two extra cancer victims per one hundred thousand persons exposed, or at least 4,400 additional lifetime cancer patients in the U.S. I might add, moreover, that we are not talking about extreme consumption patterns but rather the typical consumption of citrus. The EPA has also stated that "individuals who eat higher amounts will be subject to correspondingly higher risks." 48 Fed. Reg. 46238. That such risks are posed is not surprising, in residue testing of fumigated citrus taken from the wholesale level or point of entry into the U.S., the FDA has found enormous concentrations of the pesticide on citrus fruit; 98 percent of the products contained measurable residues and over 40% had residues above 250 parts per billion. Ten percent were contaminated with levels of EDB in excess of 3000 parts per billion. This data is highly significant because while citrus peels are not ordinarily eaten (although there is some peel usage) nor are citrus products always processed before consumption and when they are only minimal processing is conducted. Presently it is not known what portion of the residues are consumed either through physical handling or peel migration.

The industry maintains that there are no practical alternatives to the use of EDB; irradiation is not yet approved for this use and cold storage, the process that was used prior to EDB approval, is presently insufficient for the need. Yet the fact is the industry has known since 1977 that action was growing on EDB registration and at least since 1980 the industry has been provided with the regulatory instruction to find an alternative or additional cold storage capacity. In these circumstances, no complaint about surprise and lack of forewarning could possibly be. Finally, the EPA estimates that the maximum cost to industry from EDB cancellation to be approximately $25 million, and less depending on the acceptability of cold storage or irradiation. This is a trifling sum, even if passed on to consumers, when compared to the massive health risk posed by citrus fumigation with EDB.

The agency must, in addition to cancelling registrations of remaining EDB uses, quickly move to set tolerances for residues of EDB in consumer food products. Such tolerances are required by the Food, Drug and Cosmetic Act (21 U.S.C. 346a) for poisonous or deleterious pesticides and the EPA has promised to set such tolerances. 48 Fed. Reg. 46240.

Currently there are essentially no tolerances in place for EDB per se. When EDB was first registered, it was not known or believed that EDB residues would remain, thus the chemical was provided with an exemption from any tolerances, which is also authorized by the FD&C Act. While it is troublesome enough that this exemption was allowed without any good information about residues, it is scandalous that the agency did not revoke the exemption and establish a tolerance once it was learned that residues would remain and that the pesticide is a health hazard. Thus, this is the first change we would recommend in the authorizing statutes: exemptions must be revoked automatically once it is learned that the pesticide is harmful and that residues will remain.

With respect to the actual level at which tolerances are set, we believe that a zero tolerance is appropriate and that the EPA should not sanction any residue of the chemical in food products. If this is physically impossible to accomplish without banning the sale of a good portion of the food supply the EPA should be provided with the statutory power to immediately set emergency action levels for EDB residues on all food products but with the stipulation that such emergency tolerances will be extinguished within as short a period as possible and by no means longer than two years.

In the future, we believe that pesticides should not be provided with tolerances if they are carcinogenic and, equally important, that the Congress must provide stronger monitoring and enforcement authorities to the Food and Drug Administration. Currently the FDA conducts a random sampling of produce for some pesticide residues but such sampling is severely limited in scope, in terms of quantity sampled and the pesticides sampled for. Equally important, the FDA does not now have any authority to detain domestic food from entering commerce while residue testing is underway, even when food is suggested of containing excessive residues.

Nor does it have the power to recall adulterated food from the marketplace once such adulteration is confirmed.

Nor does it have the authority possessed by most other health and safety regulatory agencies, such as the EPA, to assess civil penalties on the owners or producers of product which contains excessive residue levels. The FDA is on record as supportive of efforts to provide it with these authorities; until the Congress does so, efforts to control the use of EDB will be less than effective.

Mr. Chairman, we know that this committee has no legislative jurisdiction over the FDA or the EPA. But you do have oversight authority and we believe you should obtain from the EPA a committment as to when the agency plans to set the residue tolerance for EDB required by law to protect the public health, and urge the agency to move expeditiously, to cancel, on an emergency basis the use registrations remaining for EDB use as a post-harvest fumigant. We also hope that you will join with us in urging the appropriate committees of the congress to develop legislation providing the aforementioned appropriate authorities to enhance FDA product monitoring and residue enforcement activities. The general public stands squarely behind you in these efforts.

Mr. Chairman, this includes my prepared remarks. I would be happy to respond to any questions you may have.

STATEMENT OF JAY FELDMAN
NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U.S. SENATE
JANUARY 27, 1984

Thank you for the opportunity to apprear before the subcommittee today. I am Jay Feldman, National Coordinator of the National Coalition Against the Misuse of Pesticides (NCAMP). I welcome the opportunity to speak with you today about ethylene dibromide (EDB) and the seriousness of the events that have lead to this hearing. Mr. Chairman and members of the subcommittee, you are to be applauded for responding to the EDB matter and using your oversight authority to seek answers to difficult questions.

Our coalition's concern about toxic pesticides grows out of the experiences of our broad-based network of organizations and individuals in 50 states across the country. NCAMP is composed of members with common concerns about pesticide hazards and safety, including consumers, farmers and farm workers, urban and rural residents alike.

The coalition seeks protection for all who may be exposed to pesticides, either through their employment, as consumers, as victims of contaminated drinking water, or as neighbors of dump sites, sprayed fields, forests or right-of-ways. NCAMP also promotes alternatives to excessive pesticide use and misuse, such as Integrated Pest Management (IPM) and non-chemical approaches, in an effort to reduce damage to humans and the environment, ease economic burdens over the long-run and improve general public and occupational health.

As you know by now, Mr. Chairman and members of the subcomittee, *there are no easy answers* to the EDB crisis. My presentation today is not intended to lay out three easy steps to a solution, but rather to put the EDB matter into a political, scientific and regulatory context, ask difficult questions and pose serious solutions. Be assured, the EDB problem is not without context and history. The chemical does not appear as a problem in 1984 as if by spontaneous combustion.

The Political Context of EDB and Pesticide Decision Making

While I would normally begin with a disucssion of the nature of EDB, its carcinogenic properties and its potency and urge action based on a responsible reduction or minimization of risk to society, our families, our children and our future, I will save this discussion for later. Given the serious nature of the EDB matter, we must first stop and consider how we got to the crisis and why other, just as dangerous, crises are looming on the horizon. In the overall context of an appropriate response to the EDB matter, scientific findings of risk are, unfortunately, only one factor whose importance actually wanes in the context of the political decision making process.

Unfortunately, Mr. Chairman, in the case of EDB, and for that matter with other toxic chemical pesticides, politics propels the decision making process. The history of EDB's regulation or non-regulation is a textbook study of the political process, the influence of corporate power, and the terrific impact of compromised public policy decisions which allow the proliferation of chemical catastrophes that put the entire population at tremendous risk.

We, in fact, do not in 1984 have a system of chemical pesticide controls which impose a set of objective standards, applied uniformly, in an effort to protect public health and the environment from poisoning and contamination. Instead, we have the outlines, the pretense of policy which enables chemical corporations to market toxic products, untested for their effects on human health and the environment, under a veil of secrecy and closed door meetings, all with the certification and approval of government. The political and regulatory process of controlling toxic pesticides offers more respect and protection for toxic pesticide products than it does for human life and the environment.

Where does all this bring us. Everyone in this hearing room is aware of special interest politics and its influence within our political system. One does not have to spend much time in Washington to hear that political decision making is the "art of the possible." What that translates into is a solution that meets industry needs and public interest concerns half way. This representation of the political decision making process accepts a society without applied standards of safety or with standards that are vulnerable to the political winds. This process accepts an EDB crisis building for a decade --as it has-- while the artisans of the possible weave fabrics that allow hazardous pesticide material to slip between the threads and into our food, water and air.

For purposes of toxic pesticide control, we must cut through the politics to devise a system of control that works, that is purposely not vulnerable to political pressure. If we are not committed to doing this then there is probably no reason to have a hearing of this nature. The hearing simply provides a forum for the affected industry groups to take a political posture that is protective of their investments and provides the optimum amount of regulatory flexibility.

Once we establish the commitment to safety, solutions can and must be discussed outside of a political framework which responds only after polling competing factions to determine the course of least resistance. Those opposing standards of safety, comprehensive monitoring and reporting of hazards, full and adequate testing and public disclosure must be asked to explain and justify their positions. The public cannot, however, be expected to meet a carcinogen half way.

The public will no longer accept the existing practice of asking the regulated chemical industry how they would like to be regulated. Decision makers must recognize and eliminate the conflict-of-interest inherent in current pesticide control practices and the natural inclination of the industry to maintain positions which enhance their profit margins at the expense of public health. Toxic pesticides such as EDB will not be regulated until this conflict-of-interest decision making is eliminated.

While the regulated industry resists strenuously proposals which are intended to prevent future EDB crises, it does seek EPA registration of its products, not only to comply with their legal responsibilities, but to tout as evidence of product safety. In fact, the users down the line are misled and the public is involuntarily exposed to pesticides which are not tested or are suspected human carcinogens.

Why the Concern About EDB?

According to EPA, "EDB is a potent carcinogen in laboratory animals. It has been found to cause cancer in both sexes of rats and mice in both high and low dose groups, via multiple routes of exposure and at various anatomical sites --the initial site of exposure as well as distant sites. Also, the latency period, or time-to-tumor, is very short." The Agency also concluded in 1980 that, EDB is positive in both prokaryotic (microbial) and eukaryotic (higher forms, including mammals) organisms for point(gene) mutation effects." (Position Document 2/3, Federal Register, December 10, 1980, vol. 45, No. 239, p. 81517)

Additionally, the Agency found that, "EDB would adversely affect mammalian reproductive development by interfering with the production of male gamets and the development of embryos. Adverse effects in hen egg production were also noted." (PD 2/3, Fed Reg p. 81517)

EDB is a halogenated hydrocarbon, as are DDT, chordane, heptachlor, aldrin, dieldrin and DBCP, all the subject of severe restrictions in the 1970's. The chemical has been registered as a pesticide since 1948.

Uses of EDB

Aproximately 300 million pounds of EDB are produced each year in the U.S. Ninety percent of this amount is actually used as a gasoline additive to prevent lead deposits from collecting in engine cylinders. The remaining poundage is used in soil fumigation; post-harvest quarantine fumigation of citrus and other fruits and vegetables to prevent the spread of tropical fruit flies; as a fumigant to prevent insect infestation of stored grain; as a spot fumigant for vaults, beehives, and timber; in termite control; and in certain minor industrial applications.

Prior to its emergency suspension for soil fumigation use in September 1983, 20 million pounds of EDB were applied to croplands each year. The suspension order allows this use to continue until EDB supplies are exhausted. EDB has been used on crops (including soybeans, cotton, peanuts, pineapple, and 30 other fruit and vegetable crops) for protection against nematodes (root worms). Less than 1.0 million pounds per year are used for both stored grain fumigation and spot fumigation of grain milling equipment, and less than 0.3 million pounds per year are used in all other pesticidal uses.

Despite the relatively low quantities of EDB's pesticidal uses compared to its use in leaded gasoline, EDB has been detected in more than 200 products on grocery shelves and may have contaminated the nation's entire 7.7 billion bushel grain stockpile. EDB has been found to be contaminating ground water supplies in several states resulting from its use as a soil fumigant.

Action Is Required on Three Fronts

We must act to address:

- the danger of continued EDB use;
- the public health threat associated with the continued sale of EDB-contaminated food and the consumption of tainted water, and;
- the pressing need to prevent pending health and environmental crises, such a this one, which relate directly to deficiencies in the national pesticide control law --the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The Danger of Continued EDB Use

The entry of EDB into the market place must stop immediately. EDB's ability to enter the food system through grain-based products produced with treated grain or citrus fumigated with the chemical provides the basis for a determination of "imminent danger" and the justification for emergency action. As the members of the subcommittee know, EPA already issued an emergency suspension to stop EDB's soil fumigation on September 27., 1983 because of ground water monitoring results which indicated the chemical's ability to leach through the soil.

Our position on this was actually the EPA's own position back in 1980 when it issued its findings after a special review of EDB. After issuing a Rebuttable Presumption Against Registration (RPAR) in 1977 and reviewing all available information over the following three years, the Agency "concluded that the presumptions for oncogenicity, mutagenicity and reproductive disorders have not been rebutted." (PD 2/3, Fed Reg, p. 81516).

In grain and citrus uses, EPA found that the risks arising from the uses of EDB are greater than the social, economic and environmental benefits. In the case of grain, the Agency determined that the cancellation would not have a significant impact on the production and prices of agricultural commodities, retail food prices and other segments of the agricultural economy. For the citrus use, the Agency proposed a three-year phase out which would have ended July 1, 1983 to ease the transition to alternative methods of control.

The projected cancer rates ensuing from dietary risks to the average consumer are very high. In its final position document (PD 4), EPA estimated the additional cancer risk due to bulk grain fumigation to be as high as 3.3 per 1000.

The Agency officially estimated in its PD 4 that in those states requiring EDB quarentine fumigation of citrus the additonal risk to the average individual consumer of fresh citrus (60 kg person, consuming 1.5 kg food/day) would be 2.4 per 10,000. However, a senior scientist in EPA estimates that consumption of a 200 gram middle-sized California orange treated with EDB and containing one p.p.b. would increase the risk of cancer to at least one in a thousand or possibly 50 to 70 per thousand.

It is also appropriate to require a stop sale order as part of any emergency action on EDB. This was not done when the September, 27 emergency suspension of EDB's soil fumigation took effect. As a result, EDB's "suspended" uses continue until supplies are exhausted.

The Public Health Threat Associated with Continued Sale of EDB-Contaminated Food and Consumption of Tainted Water

EPA has no choice but to set a zero tolerance for EDB and seek to eliminate this carcinogen from the food supply. To do this, EPA must revoke a 1956 Food and Drug Administration exemption adopted by EPA in 1976 which exempts EDB residues from tolerances (with the one exception being soybeans).

While we believe it is correct to focus concern on levels of EDB in the end food product rather than the raw agricultural commodity, proponents of action strategies, in considering the volatile nature of EDB, must respond to the possible inhalation hazard to those heating and baking EDB-laced products in their home. EPA's PD 2/3 cites EDB inhalation studies which "demonstrates that this exposure route causes deleterious effects upon reproductive tissue." (PD 2/3, Fed Reg, p. 81518). Other studies indicate that inhaled EDB produces a statistically significant increase in tumors of several sites in exposed asnimals.

EPA states that it does not have the authority to set indoor pesticide residue standards. In a January 17, 1983 letter explaining federal policy, the former Deputy EPA Administrator, John Hernandez, said the setting of maximum residual levels or tolerances for pesticides with indoor uses is outside the Agency's legal authority. He states, "Neither the Federal, Food, Drug and Cosmetic Act, the FIFRA, nor any other pertinent statutes, provide for setting of maximum residues of pesticides in air or on surfaces in buildings."

Given the inhalation data, if the sale of raw, uncooked EDB-contaminated food products continues, an indoor air standard may prove necessary to protect people in their homes.

Meanwhile, the water contamination resulting from EDB's now suspended soil fumigation use still poses a threat to public health in four states --California, Florida, Georgia and Hawaii-- where levels of EDB were detected. EPA has presented lifetime cancer risks, assuming two liters of water consumption per day for an adult, a 60 kg lifetime average weight and a 70 year lifetime: 0.02 p.p.b. EDB equals a cancer risk of 3 in 100,000;

0.1 p.p.b. equals 1.5 in 10,000; 1 p.p.b. equals 1.5 in 1,000; and 100 p.p.b. equals 1.5 in 10.

While EPA has identified the hazards, states are left on their own to try to clean up the water and individuals must often seek clean water at their own expense. The U.S. Congress must authorize an emergency ground water clean up program in the contaminated areas and in the interim provide safe drinking water to those who cannot afford to buy it.

Underlying Deficiencies in the National Pesticide Control Law --the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

The status of EDB over the last 14 years is representative of thousands of other chemical pesticide products whose widespread uses have gone unregulated and have continued to evade regulation while little is known about their health and environmental effects. Although EDB was caught in the regulatory net due to a National Cancer Institute study, this has not been the case with most of the thousands of pesticide products registered prior to the adoption of the 1972 amendments to FIFRA.

While FIFRA requires the re-registration of older chemicals, EPA has never fulfilled its responsibility in this area. EPA is moving to carry out a generic review of the basice 600 active ingredients composing approximately 35,000 products on the market. The review should for the first time centralize EPA's informaton on each active ingredient. The Agency has only completed 64 of these generic registration standards. Moreover, this standard is only the first step in the process to actually reassess product safety.

If EDB had been registered in a timely manner and brought into compliance with standards of safety created in the early 1970's, the EDB problem would have been solved years ago. Similarly, thousands of products are in wide use today and are out of compliance with modern standards of safety.

FIFRA contains incentives for the continued marketing of these untested products. Pesticides which entered the marketplace prior to the creation of the stricter safety standards of the 1970's remain on the market without adequate incentives for manufacturers to fill health and safety data gaps and replace faulty or fraudulent data. For instance, between 79 and 84 percent of the products on the market have not been adequately tested for their capacity to cause cancer. Similarly, between 90 and 93 percent of the same products have not been adeqautely tested for their ability to cause genetic damage. Between 60 and 70 percent have not been fully tested for birth defects, and between 30 and 46 percent have not been fully tested for reproductive effects. (Staff Report, EPA Pesticide Regulatory Study, Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, 97th Cong., 2nd Session, December 17, 1982, p. 187)

If manufacturers want to expand the market for their untested products or market a new product prior to the completion of health and safety studies, they may avoid the standard registration process and enter the market through the less rigorous routes of emergency exemptions and/or special local need permits. The use of emergency exemptions rose 352 percent from FY 1978 to FY 1982. Special local need permits jumped to 1,656 in FY 1982, rising from 440 in FY 1976.

Manufacturers know that if their product is found to be deserving of a ban, they can be indemnified under FIFRA's indemnification provision (which pays manufacturers for losses resulting from an EPA ban on continued sales and use) or, at the least, permitted to exhaust existing supplies, as was the case with the EDB suspension order. This, together with loose standards, creates a disincentive for manufacturers to develop important health and safety data on their products in a timely manner. Further, the indemnification program under FIFRA creates a disincentive for EPA to regulate. Regulation can end up costing the government money. Finally, taxpayers under the current system in the end pay for industry misconduct.

Legislation has been introduced in the U.S. Senate and the House of Representatives to correct the deficiencies in the law which EDB has so graphically demonstrated. The legislation is called the Federal Insecticide, Fungicide and Rodenticide Reform Act, S. 1174/H.R. 3818. It has been endorsed by virtually every major environmental groups, AFL-CIO member unions and health and consumer groups.

The legislation would assure that pesticides are fully tested and registered within a specific time period if they are to remain on the market. The bill also adjusts the incentives of FIFRA to assure industry compliance with safety standards in an orderly fashion. By way of example, despite the fact that manufacturers of EDB were alerted as early as 1975 that their product was a suspect carcinogen, they continued to market their product while exhausting administrative remedies and holding "closed door" decision conferences with regulators. These action appear to have extended the product's life until today. While FIFRA, as written, enables bad faith marketing, S. 1774 would put an end to this. Because the bill incorporates a registration fee system and eliminates the indemnification program, we predict that increased program costs will be offset by a revenue generation program and cost savings.

S. 1774 takes a comprehensive look at the control of pesticides and attempts to close loopholes in the registration program, gather more information about pesticides, improve protection of humans, increase public input on pesticide decisions and improve enforcement of the pesticide law.

Conclusion

The EDB crisis represents a dramatic threat to the health of the nation if it is allowed to continue. The situation requires immediate action. The action steps we have recommended may require Congressional action to assure an expeditious response. Meanwhile, EPA Administrator William D. Ruckelshaus has promised to announce his plans for EDB and EDB-contaminated food products by the end of this month.

Mr. Chairman and members of the subcommittee, we urge you to carefully follow the actions of EPA in this area and assure a response along the lines we have suggested.

Attachment #1

National Coalition Against the Misuse of Pesticides
530 7th Street, S.E. • Washington, D.C. 20003 • 202/543-4313

ETHYLENE DIBROMIDE (EDB)

Fact Sheet

Uses

Approximately 300 million pounds of EDB are produced each year in the U.S. Ninety percent of this amount is used as a gasoline additive to prevent lead deposits from collecting in engine cylinders. The remaining poundage is used in soil fumigation; post-harvest quarantine fumigation of citrus and other fruits and vegetables to prevent the spread of tropical fruit flies; as a fumigant to prevent insect infestation of stored grain; as a spot fumigant for vaults, beehives, and timber; in termite control; and in certain minor industrial applications.

Prior to its emergency suspension for soil fumigation use in September 1983, 20 million pounds of EDB were applied to croplands each year. The crops (including soybeans, cotton, peanuts, pineapples, and 30 other fruit and vegetable crops) were to be protected from attack by nematodes (root worms). Less than 1.0 million pounds per year are used for both stored grain fumigation and spot fumigation of grain milling equipment, and less than 0.3 million pounds per year are used in all other pesticidal uses.

Despite the relatively low quantities of EDB's pesticidal uses versus its use in leaded gasoline, EDB has been detected in more than 200 products on grocery shelves and may have contaminated the Nation's entire 7.7 billion bushel grain stockpile. EDB has been found to be contaminating ground water supplies in several states resulting from its use as a soil fumigant.

History

- The National Cancer Institute (NCI) issued a preliminary notice in 1975 that EDB appeared to induce cancer in laboratory animals.
- In 1976, EPA updated a tolerance exemption for organic bromide (including EDB) residues on foods which had been issued by the Food and Drug Administration in 1956. Barley, corn, oats, popcorn, rice, rye, sorghum (mild), and wheat are exempt from a tolerance for residues of EDB. This exemption also applies to foods processed with EDB-treated grains. The exemption of EDB from a tolerance for residues under EPA regulation has the effect of exempting EDB from the provisions of the Federal Food, Drug, and Cosmetics Act, administered by the Food and Drug Administration.
- In 1977, EPA identified literature citing EDB as a carcinogen, relying on a study sponsored by NCI (Weisburger, 1977). At that time, EPA issued a Notice of Rebuttable Presumption Against Registration (RPAR) and began a special review of the pesticide while it remained in use.

- Three years later, in 1980, EPA issued a preliminary decision (published in the Federal Register, vol. 45 no. 239, December 10, 1980, p. 81516) which called for the immediate cancellation of EDB use on stored grain, flour mill machinery, and felled logs; a phase out of post-harvest fumigation of citrus by July 1, 1983; and the continued use of EDB as a soil fumigant and in certain minor pesticidal uses, subject to restrictions.

- On September 28, 1983, EPA ordered the immediate emergency suspension of EDB as a soil fumigant for agricultural crops. At the same time, the Agency announced the cancellation and phase out of all major pesticidal uses of EDB. EPA cited significant new evidence that EDB has been contaminating ground water supplies in a number of states.

- In October 1983, chemical manufacturers and users of EDB challenged EPA's intent to cancel EDB for grain fumigation and/or spot treatment and grain milling machinery uses. Cancellation does not take effect on these uses pending administrative hearings.

Health and Environmental Problems

According to EPA, "EDB is a potent carcinogen in laboratory animals. It has been found to cause cancer in both sexes of rats and mice in both high and low dose groups, via multiple routes of exposure and at various anatomical sites--the initial site of exposure as well as distant sites. Also, the latency period, or time-to-tumor, is very short."

The Agency also concluded in 1980 that, "EDB is positive in both prokaryotic (microbial) and eukaryotic (higher forms, including mammals) organisms for point (gene) mutation effects."

Additionally, the Agency found that, "EDB would adversely affect mammalian reproductive development by interfering with the production of male gametes and the development of embryos. Adverse effects in hen egg production were also noted."

EDB is a halogenated hydrocarbon, as are DDT, chlordane, heptachlor, aldrin, dieldrin and DBCP, all the subject of severe restrictions in the 1970's. EDB has been registered as a pesticide since 1948.

- Food Contamination

When EPA announced its decision in 1980 to take emergency steps to ban uses of EDB on stored grain and grain milling machinery, the Agency found evidence that EDB residues can occur in food products as a result of grain milling and machinery fumigation. Three years later, EPA did not act decisively on its original findings and as a result the burden was on the States to protect the public.

The State of Florida recalled 77 common grain-based products during December, 1983 after finding levels of EDB ranging from less than 1 p.p.b. to 755.70 p.p.b. Tests in Texas confirmed many of these findings.

A senior scientist at EPA estimates that a "200 gram middle-sized California orange with merely 1 p.p.b. of EDB would provide each day some 50-70 times the dosage viewed as safe at a 10^{-3} (1 in 1,000) upper limit on the risk; consumption of additional food fumigated with EDB would clearly increase the risk even more." This translates to a risk of one in a thousand or possibly 50 to 70 per thousand.

- Ground Water Contamination

After its 1977-80 review, EPA in March 1982 was notified that EDB residues in ground water had been detected in Georgia. In June 1983, California monitoring found EDB contaminated ground water in areas of soil fumigation use. Then, wells in Hawaii and Florida were also found to be contaminated. The Department of Health in Hawaii and other states were warned in a September 23, 1983 letter from EPA that EDB in the water at a 20 p.p.t. level of detection is not safe.

"There is a significant lifetime cancer risk for the general population even at the detection limit, for lifetime exposures. Therefore, we recommend that, as the EDB detection levels drop you balance consideration for alternative water sources or treatment capability against the projected cancer risks and use this process to decide whether to close wells," the EPA letter reads.

The EPA presented lifetime cancer risks, assuming 2 liters of water consumption per day for an adult, a 60 kg lifetime average weight and a 70 year lifetime: 0.02 p.p.b. EDB equals 3 in 100,000 cancer risk; 0.1 p.p.b. equals 1.5 in 10,000; 1 p.p.b. equals 1.5 in 1,000; and 100 p.p.b. equals 1.5 in 10. The letter warns, "The numbers presented above are exclusively for EDB exposure via drinking water. Significant exposure via other routes over the same period of time would cause these risk estimates to change proportionately."

Action Required

As a result of the potential for carcinogenicity exhibited by EDB and the multiple routes of exposure by humans that have been detected, immediate action is required to both regulate the pesticide product and to address the question of contaminated food and water. The burden that has been thrown on the states and on individuals by virtue of an ineffective national pesticide control law--the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)--and a politically vulnerable EPA is blanketly unfair.

The situation requires immediate Federal attention. The U.S. EPA is not moving in a sufficiently quick and decisive manner to respond to the hazards posed by EDB to the American public. Administrator Ruckelshaus' program for monitoring is not acceptable because it will allow EDB to continue to enter the nation's food supply. There is sufficient evidence on the table now to stop the entry of EDB into the food supply and to stop the sale of contaminated products. Monitoring schemes, although needed to identify priority clean-up areas, should not be used as substitutes for decisive actions. The National Coalition Against the Misuse of Pesticide calls for immediate action to:

- Ban all uses of EDB;
- Recall all foods and food products with detectable levels of EDB;
- Assist the States with an emergency program to provide safe, clean drinking water to those who cannot afford to buy it and to clean up contaminated drinking water; and
- Repeal the indemnification clause of FIFRA so that industry, not the taxpayer, pays for the clean up of contaminated areas and for the losses associated with an emergency ban on EDB uses.

Statement

By

Thurman L. Boykin

Washington Representative

THE AGRISTORE COMPANY

January 27, 1984

For Inclusion in the Record of
the Hearing Held January 27, 1984

By

The Sub-committee on Toxic Substance and
Environmental Oversight of the Senate
Committee on Environment and Public Works

Honorable David Durenburger, Chairman

Mr. Chairman and Members:

We appreciate the invitation to submit this statement, and it is an honor to do so.

We feel it important to bring to the Sub-committee's attention the discovery and domestic availability of the most perfect facility for permanent and temporary grain storage yet developed this century. Two of its most pertinent attributes are that its chamber is a combustion-free atmosphere and that it does not require the addition of fumigants for the maintenance of its deterioration free condition. It is the Agristore, a flexible membrane system.

Success in overseas use has been so superior that we, the American market developer, have succeeded in obtaining insurer agreement to insure the facility's stored contents against loss of quaility. Those crops which have been stored in the flexible membrane system are corn, wheat, milo, rice, cottonseed, sorghum grain, pinto beans, soybeans and coffee beans.

The Agristore is an astonishingly uncomplicated facility and system in both method and materials. It is a horizontal structure of special high strength polyvinylchloride (PVC). The PVC is manufactured here in the United States to the Company's specifications. The Agristore PVC has withstood strength tests for use in extreme cold and heat and thus can be used in any climate. An Agristore is tailored and installed on site for both large and small storage.

In our opinion it is destined to have the greatest impact on post harvest food loss and thus world hunger of any development yet accomplished.

Clearly, put, the reason that the addition of fumigants is unnecessary is that once the grain is sealed inside using Agristore's bonding process, the stored grain rapidly absorbs the trapped oxygen and gives off carbon dioxide (CO_2). Insects can not live therein plus the aging process is slowed dramatically, and the grain preserved for long periods of time, even years.

One of the United States' grain sales competitors, Australia, has embraced the flexible membrane system concept strongly. Loss of grain stored in Agristore-like structures in Australia approximates 0.5% according to the Australian Wheat Board. This further substantiates our claim that the prefected facility is deterioration-proof. Documents recently provided us on the state-of-the-art in Australia will be put on file with the Sub-committee staff for your scrutiny. Also we will provide a copy of the current British Overseas Development Agency report on testing of flexible vertical storage in tropical areas. Do recognize that the vertical facilities are earlier efforts using a complicated plastic and metal structure. The Agristore's simplicity and superior PVC have outdated the European effort.

I, as a proponent of this phenomenon, feel it important that we as a nation communicate the potential impact of the flexible system to the hungry nations of our world. I feel this communication is not too far off. I maintain that the flexible membrane system's impact on world hunger will be of a magnitude similar to the Salk vaccine discovery's on the dread polio. President Eisenhower ordered news of that discovery dissiminated by our State Department to 75 nations. I advocate that America tell the world of this development.

The U.S. Department of Agriculture (USDA) has issued a memorandum to its ASCS field office that the flexible membrane facility is accepted for storage of Commodity Credit Corporation grain on a case by case basis. The Company has authorization to provide you the name and address of Mr. Charles Witham of Kansas, a farmer who has personal experience using an Agristore for storing a recent pinto crop on his farm.

Mr. Charles Witham
Western Seed and Supply Company
P.O. Box 327
Leoti, Kansas 67861
(316) 375-4429

Two individuals who hold key positions in our government acquainted with the Australian experience or recent developments in long-term flexible storage are Dr. Kenneth Gilles of USDA's Federal Grain Inspection service and Dr. Robert Morris of USAID's Bureau of Science and Technology.

In July 1983, sixteen Senators and Congressmen urged Secretary of Agriculture John Block to commence testing the flexible membrane system. I am pleased to call to the Members' attention that the Sub-committee Chairman was a signer of the letter, a copy of which is enclosed. Those tests are not yet underway though several USDA officials acknowledge the great promise of the Agristore.

Domestic storers can begin using the Agristore at the next harvest as auxiliary storage and may need never call on additional fumigant-requiring grain storage again. Should an Agristore user wish to add a fumigant, it may be safely accomplished using injections or blankets of additional CO_2 or phosphine. We are making available a document from the Commonwealth Scientific and Industrial Research Organization detailing test experience with phosphine and a document detailing experience with injections of CO_2 in Indonesian testing.

Mr. Stephen Stoughton, President of the Agristore Company, joins me in sincerely thanking you for this opportunity.

RICHARD G. LUGAR
INDIANA
SH 306 SENATE OFFICE BUILDING
WASHINGTON, D.C. 20510
202-224-4814

COMMITTEES:
FOREIGN RELATIONS
AGRICULTURE, NUTRITION AND FORESTRY
SELECT COMMITTEE ON INTELLIGENCE

United States Senate
WASHINGTON, D.C. 20510

June 22, 1983

The Honorable John R. Block
Secretary of Agriculture
Department of Agriculture
14th and Independence Streets, S.W.
Washington, D.C. 20250

Dear Mr. Secretary:

It is our understanding that the ARS, in conjunction with the ASCS, is considering a research demonstration project to evaluate and test the long-term grain storage potential of the flexible membrane storage facility. We wish to urge your prompt approval of this research project.

In previous correspondence with the developers of the flexible membrane system, the USDA has indicated its reluctance to go forward with the demonstration because of the $500,000 cost of the research project. While we highly commend your efforts at controlling costs, we believe that a successful demonstration project will eventually result in substantially greater savings to the Commodity Credit Corporation and the U.S. taxpayer.

In this age of rising government storage costs, we must not overlook the possible advantages such an inexpensive storage system offers to farmers as well as taxpayers. We further must study and become familiar with the facility's efficiency in the most expeditious and cost-effective manner. We appreciate departmental sensitivity to these factors in the test plans that have been arranged by ASCS and ARS.

While the flexible membrane system has had broad acceptance outside this country, it has not experienced widespread use here at home due to farmer and warehouseman hesitation to accept it without USDA sanction through granting of conventional storage status. We appreciate and respect the reluctance on the part of the USDA in approving a nonconventional storage system without sound testing data. In this regard, the results of a modest testing program would provide the USDA with the data necessary to evaluate this system's usefulness.

We consider this activity to be an appropriate and important research endeavor which can provide our farmers and warehouseman answers to pressing storage questions. Given the USDA's recent expenditures for storage payments, indeed, one of the most pressing research needs is the discovery of a more efficient post-harvest storage system.

For these reasons, we hope you will lend your support for this demonstration project. Thank you for your immediate attention to this matter.

Sincerely,

Bob Dole
Robert Dole

Dick Lugar
Richard G. Lugar

John C Stennis
John C. Stennis

Thad Cochran
Thad Cochran

David L. Boren
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United States
Department of
Agriculture

Office of
the Secretary

Development of Alternative Technologies for Quarantine Treatment of Fruits and Vegetables

Prepared by the U.S. Department of Agriculture
as requested by the Congress of the
United States of America

February 15, 1984

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Issued February 15, 1984

PURPOSE

The Secretary of Agriculture was directed to establish and lead a task force on the development of new post-harvest insect infestation treatments of fruits and vegetables by the U.S. Congress (House Report No. 98-450 of October 27, 1983, and House Report No. 98-231 of June 3, 1983). This request was made because the Environmental Protection Agency published in September 1983, a notice of intent to cancel the use of EDB for the fumigation treatment of fruit and vegetables to be effective September 1, 1984, if not contested. The Congress requested that the Secretary report the findings of the task force to the appropriate committees of Congress by February 15, 1984.

Assistant Secretary for Science and Education, Orville G. Bentley, assembled a task force comprised of 7 Department agencies: Agricultural Marketing Service, Agricultural Research Service, Animal and Plant Health Inspection Service, Cooperative State Research Service, Economics Research Service, Foreign Agricultural Service, and Office of Transportation. Also, information was requested from the Department of Health and Human Services, and the Environmental Protection Agency. The following text and reference material fulfill the request.

REFERENCES

1. EPA Position Document 1 on Ethylene Dibromide, December 1977
2. USDA, EPA, State Universities, Assessment Report on Ethylene Dibromide, June 1980
3. EPA Position Document 2/3 on Ethylene Dibromide, December 1980
4. USDA Report of Research on the Effect of Ethylene Dibromide Citrus Fumigation on Fruit Fly Control and Residue Levels, September 1983
5. Risk Assessment/Risk Management Report on Consumption of Treated Citrus, September 1983
6. EPA Position Document 4, September 1983
7. USDA Plant Pest Act and Plant Quarantine Act
8. Regional Project on Post-Harvest Insect Control
9. Protocol for Control of Mexican Fruit Fly in Texas

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I. BACKGROUND

A. Ethylene Dibromide Registration History

ETHYLENE DIBROMIDE (EDB) has been produced in the United States since the 1920's and is used primarily as a lead scavenger in leaded gasoline additives. It has been registered as a pesticide since 1948. Of the estimated 300 million pounds produced each year, only 5 to 7% was used in the agricultural pesticide market until September 1983.

The largest agricultural use of EDB has been the soil fumigation use (soybeans, cotton, peanuts, tobacco and pineapples, as well as a number of other fruit and vegetable crops). This use for nematode control accounted for more than 80% of all the U.S. EDB pesticide product until banned in 1983. The Administrator of the Environmental Protection Agency (EPA) announced on February 3, 1984, emergency suspension of EDB use for stored grain fumigation and spot fumigation of grain milling machinery. The only remaining registered uses of EDB are for quarantine fumigation of fruits and vegetables (less than 100,000 pounds/year) and smaller amounts are used for fumigation of beehives, storage vaults, and termite control.

U.S. quarantine fumigations are treatments authorized by the Federal Plant Quarantine Act of August 20, 1912, and the Federal Plant Pest Act of May 23, 1957. These treatments are carried out to prevent the introduction or interstate dissemination of new insect pests or diseases. Foreign insects invading a new location frequently become more destructive than in their native habitat because of the absence of natural predators and diseases and lack of competition for food sources. Other countries, Japan for example, require treatment of certain U.S. fruit and vegetables for precisely the same reason: to prevent insects and diseases from becoming established in their country.

The first indication of a potential problem with EDB was contained in a September 4, 1973, letter to EPA from Dr. Weisburger of the National Cancer Institute (NCI), stating that EDB produces "a high incidence of squamous cell carcinoma of the stomach" when administered at high doses during chronic feeding studies conducted with rats and mice. On October 16, 1974, NCI issued a "Memorandum of Alert" regarding the preliminary finding of carcinogenic activity.

The (EPA) placed the chemical under review in November of 1975. Based upon the NCI cancer study, information on mutagenicity, possible adverse reproductive effects, and a review of available literature, EPA issued a notice of Rebuttable Presumption Against Registration along with a Position Document Number One in the December 14, 1977, Federal Register (Reference 1).

The USDA, in cooperation with EPA, pursuant to a memorandum of understanding, established a pesticide impact assessment team (composed of USDA, State and EPA personnel) to assess the benefits and potential exposure resulting from registered uses of EDB as an agricultural pesticide. Their June 1980 report was made a part of the EPA rebuttable presumption file (Reference 2). The overall impact resulting from a cancellation of EDB at that time was estimated to be between $57.8 million and $62.7 million. This included increased cost of treatment as well as decreased value of production.

EPA issued a preliminary notice of regulatory decision in December 1980, Position Document 2/3 (Reference 3). At that time the Agency proposed to ban the use of EDB as a fumigant of stored grain, grain milling machinery, and felled logs and to phase out by July 1983 the quarantine use on citrus, tropical fruits and vegetables. The preplant soil fumigation use was to be retained. This preliminary notice was forwarded to the Secretary of Agriculture for comment as required by law.

On April 6, 1981, Secretary Block responded to EPA's December notice. In summary the Department concurred in EPA's decision to continue use of EDB for soil fumigation and the postponement of a decision on several other uses pending receipt of additional data. The Department did not agree that EDB use should be canceled for fumigation of felled logs or for quarantine purposes. There was insufficient information to adequately indicate that gamma irradiation was or would be a feasible substitute for EDB quarantine fumigation on a broad scale basis by the proposed July 1983 phase-out date. USDA suggested that more data on residue levels as well as information on the effectiveness of worker and applicator protection techniques.

On September 13, 1983, at the request of EPA, the Department provided residue data on citrus treated with reduced dosages of EDB (Reference 4). Also, at EPA's request on September 15, a draft risk assessment with more recent data on the distribution of risk to the California population from consumption of treated citrus was provided. As promised, the completed risk assessment/risk management report was transmitted on September 30 (Reference 5).

It was also on September 30, 1983, that EPA published their Position Document Number 4, announcing their decision of September 28, to issue a notice of emergency suspension of EDB as a soil fumigant and notice of intent to cancel uses on stored grain, spot fumigation of grain milling machinery, and felled log fumigation, with a phase-out by September 1, 1984, of the quarantine use (Reference 6). The termite, beehive supers, and vault fumigation uses would remain registered if certain label changes were made. Objections to the notice of intent to cancel and requests for a hearing were filed by registrants and users of EDB within the 30-day period allowed by law. The Department also filed as an intervenor to assist in the development of a complete record of scientific information and market impact.

B. The Quarantine Pest Problem

1. Domestic Considerations

The risk of introducing or spreading potential insect pests with movements of plants, plant products, and articles capable of harboring plant pests varies greatly depending upon the commodity involved and the origin of the commidity. The detection, control, eradication, suppression, and prevention or retardation of the spread of plant pests are necessary to protect the agriculture and economy of the United States and the health and welfare of the people of the United States.

The Secretary of Agriculture is authorized to take the measures he deems necessary to prevent the introduction and interstate dissemination of plant pests new to or not widely prevalent or distributed within and throughout the United States (Reference 7).

The Department's Animal and Plant Health Inspection Service (APHIS), has the responsibility to prevent the introduction and dissemination of plant pests. State plant health regulatory agencies have the responsibility to prevent intrastate spread of pests. Further, in the absence of a Federal quarantine, States are free to impose whatever quarantine restrictions they deem necessary to prevent the introduction of plant pests. When Federal quarantines are in force, there are normally parallel State quarantines to support a cooperative exclusion effort.

The Plant Protection and Quarantine (PPQ) Division of APHIS uses a variety of resources in determining the occurrence of plant pests in foreign countries. Once it has been determined that a plant pest not present in the United States, does in fact occur in a country wanting to ship products to the United States, then procedures are developed that render a host product safe to enter the United States. In most cases, this action requires chemical treatment. The same procedures apply within the United States for movements of host commodities between States for pests with limited distribution. Likewise, many foreign countries require treatment of U.S. grown commodities to provide protection from pests occurring in the United States but not occurring in the receiving foreign country.

Tropical fruit flies are insects of quarantine significance which occur at various places throughout the world as shown in Table 1. Three of the most economically important fruit flies to citrus, tropical fruit, and cucurbits (e.g., squash) that do not occur in the continental United States are the Mediterranean fruit fly (Medfly), the oriental fruit fly, and the melon fly. All three occur in the Hawaiian Islands. The first two occasionally establish themselves in the continental United States but are quickly eradicated. As an example, Medfly has been introduced into the United States four times since 1975, and with the exception of the recent California situation, all were eradicated in less than 6 months. When a fruit fly does become established, such as the recent California outbreak, cost to eradicate the pest can run into the millions of dollars. The cost for the 1982 California Medfly outbreak was $100 million. Therefore, as a condition of entry into the United States, any host commodity from a foreign country where flies are known to occur, must be quarantine treated to rid the insect from the product.

Within the continental United States, the Caribbean fruit fly (Caribfly) exists only in Florida, and the Mexican fruit fly (Mexfly) is established in Texas and was recently found in some areas of California. While there is no Federal quarantine on Caribfly, the other citrus-producing States require treatment of Florida citrus to rid the fruit of the pest as a condition of entry into their States. There is a Federal quarantine on host commodities in Texas and the regulated areas of California because of the Mexfly. In the international arena, all citrus, with the exception of limes and lemons, and tropical fruits from the Caribbean area including Mexico, must be treated as a condition of entry into the United States because of the occurrence of fruit flies that are pests of agriculture products in this geographical area.

[illegible]

Insects of Quarantine Significance

Species	Distribution	Major Hosts*
Anastrepha ludens (Mexican Fruit Fly)	Central America, Mexico, and southern Texas	Grapefruit, orange, tangerine, citron and other citrus, mango, plum, papaya, peach, apricot, nectarine, avocado, apple, pear
Anastrepha fraterculus (South American Fruit Fly)	Mexico, Central America, Argentina, Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, Uruguay, Venezuela,	Grapefruit, orange, tangerine, citron and other citrus, mango, plum, papaya, avocada, peach, apple, pear
Anastrtepha suspensa (Caribbean Fruit Fly)	West Indies: Cuba, Jamaica, Hispaniola, Puerto Rico. Found in southern and central Florida	Grapefruit, orange, and other citrus, mango, and peach
Ceratitis capitata (Mediterranean Fruit Fly)	Reported from 81 countries and political territories. Occurs in Africa, Europe, Middle East, western Australia, South and Central America, Mexico and Hawaii	Orange, grapefruit, tangerine, citron and other citrus, mango, plum, peach, apricot, nectarine, fig, persimmon, apple, pear, avocado
Dacus dorsalis (Oriental Fruit Fly)	Occurs in Asia and Pacific Islands: Bangladesh, Burma, Bonin Islands, China, Cambodia, Hawaiian Islands, India, Indonesia, Laos, Malaysia, Nepal, Okinawa, Pakistan, Philippines, Ryukyu Islands, Sri Lanka, Taiwan, Thailand, and Viet Nam	Orange, grapefruit, tangerine, and other citrus, papaya, mango, banana, pineapple (other than smooth cayenne), peach, fig, avocado, apple, pear
Dacus cucurbitae (Melon Fruit Fly)	Occurs in Asia: Afghanistan, Bangladesh, Brunei, Burma, China (including Taiwan), Hong Kong, India, Indonesia, Jammu and Kashmir, Japan (only Ryukyu Islands), Kampuchea, Malaysia, Nepal, Pakistan, Philippines, Singapore, Sri Lanka, Thailand, and Viet Nam; in Africa: Egypt, Kenya, Mauritius, Reunion, and Tanzania; and in Pacific Islands: Hawaiian Islands, Guam, and Papua, New Guinea	Cucumber, cantaloupe, squash, grapefruit, orange, papaya, mango, string bean, peach, peppers, fig, tomato, avocado, apple, pear

* Not complete host list; represents those commodities imported in the United States.

USDA, in late 1983, met with the United Fresh Fruit and Vegetable Association (United) to discuss development of alternatives to EDB. This organization represents a broad spectrum of citrus and papaya interests, both on the mainland and in Hawaii. United and its membership accepted the responsibility providing oversight to the development of alternative technology. Two technical work groups were established, one to address issues relative to citrus, the other relative to papayas.

In mid-October 1983, USDA scientists met with the citrus work group to identify candidate alternatives to EDB, set priorities on research and development efforts, and establish timetables for implementation of new technology. A followup meeting was held on January 16, 1984, to review progress. The citrus work group has representatives from the State Governments of Florida and Texas. A description of the progress to date is given in Section II. A., with target dates given in Table 4.

In mid-November 1983, the same USDA scientists met with the Hawaiian Papaya Administration Commission and papaya producers in Hawaii. The same approach outlined above was followed at this meeting. A meeting will be held in mid-February 1984 to assess progress on development of EDB alternatives for papaya treatment.

2. International Considerations

The focal point of U.S. concern for the use of EDB in the export sector has been the movement of fresh produce to Japan. Japan is one of the largest offshore markets for fresh produce and is the largest single market for fresh U.S. citrus. In fiscal year 1983, the value of U.S. exports of fresh citrus totaled $185 million. According to Japanese Government requirements, all citrus shipped from the State of Florida must be quarantine treated since fruit produced in that State is host to the Caribfly. It is estimated that at least 85% of the fresh grapefruit shipped to Japan originates in Florida.

The citrus producing areas of California and Arizona are prominent in the shipment of fresh lemons and oranges to Japan (imports of oranges into Japan operate under a limited quota). However, quarantine treatment is not presently required by the Government of Japan on California or Arizona citrus.

EDB is very widely used in Japanese agriculture for shipments to the Japanese mainland from the Ryukyu Islands as well as in shipments into Japan of fresh produce grown in Southeast Asia. Thus far, Japan has not taken any action against the use of EDB. It is well known that other countries in the Far East, especially Taiwan, are monitoring the Japanese situation closely. Should Japan rule against the further use of EDB, these other countries are expected to follow without hesitation. The only feasible alternative to EDB for the Japanese market is considered to be cold treatment (See also Section II. B. 1. a. for a detailed description), which received Government of Japan approval in late 1983. The first test commercial shipment of cold-treated fresh Florida grapefruit of the 1983-84 season arrived in Japan on November 24, 1983. A question has developed however, regarding the ability of the cold treatment process to maintain an acceptable quality level. Despite indications that the other shipments of cold-treated grapefruit arrived in generally good condition, the Japanese trade has reported some concern about early season fruit. Further details are discussed on Page 14, II B 1 a.

The use of gamma irradiation is a longer-term possibility as an alternative technology to EDB fumigation on products shipped to Japan. Its use to inhibit sprouting of potatoes was approved by the Japanese Government in 1972 and has been in use since that time. A wide range of irradiation research on various food items (including rice, wheat, onions and oranges) was conducted in Japan from 1967 to 1981. Despite results showing safety for human consumption, to date the use of irradiation on foodstuffs other than potatoes has not, been approved by the Government of Japan, apparently in deference to the deep-rooted public sensitivity to irradiation.

The U.S. Agricultural Counselor's office has contacted officials of Japan's Ministry of Agriculture, Forestry and Fisheries, and Ministry of Health and Welfare, concerning Japan's possible acceptance of irradiated papayas from Hawaii. However, officials in both Ministries were very reluctant to discuss the subject and refrained from making any specific comments on the possibility of Japan's approval for irradiated food imports. Failure to provide some alternative for the papaya shippers and growers could have considerable impact upon the Hawaiian industry. In both fiscal years 1982 and 1983, U.S. exports of fresh papayas to Japan approximated $3.6 million.

3. Imported Commodities

A decision to ban the use of EDB in quarantine fumigation will have a negative economic impact upon many countries exporting tropical fruit to the United States. At the present time, concern is most acute in those countries which will participate in the President's Caribbean Basin Initiative (CBI), which is to become effective in 1984. This program is designed to promote and develop economic incentives, especially the export potential of countries in the Caribbean region. The centerpiece of the CBI is a 12-year period of duty-free access to the U.S. markets for almost all products from the beneficiary countries. Thus, should no viable alternative be found to replace EDB fumigation for quarantine insect control, entry of commodities that carry fruit flies from Caribbean countries would be denied.

The American Embassy in Costa Rica recently sent a message to the U.S. Department of State urging that EPA take immediate action to extend the deadline on the ban of EDB for quarantine fumigation in order to allow more time to develop or change fumigation procedures that would be acceptable to USDA's Plant Protection and Quarantine, U.S. Food and Drug Administration, and U.S. EPA. The message recognized the considerable time and effort already devoted to develop the CBI incentives only to be faced suddenly with a decision that "slaps hard at potential export activity from CBI countries." Many of the 12 U.S. Embassies in the Caribbean have expressed full support for the Costa Rican message.

A preliminary survey was made of the U.S. imports subject to EDB treatment from those countries eligible for benefits under the Caribbean Basin Recovery Act for the two most recent fiscal years, 1982 and 1983. This review indicated that the commodities most affected would be, by far, mangoes and various types of fresh citrus, as well as papayas. In fiscal year 1983, the total value of such imports was $4.3 million, of which $3.9 million represented mangoes alone. Countries most affected were Haiti, Belize, Jamaica, and the Dominican Republic. Table 2 gives a list of countries and products from which EDB-treated fruit was received in FY 1982.

Though these import levels are only a reflection of the recent past, it is expected that with duty-free treatment, the production and marketing of tropical fruits will increase both in the region of the Caribbean Islands and Central America. There has already been some imports of vegetables from certain countries of Central America, the most prominent of which is Guatemala. Now, with access to a duty-free market under the CBI program, this practice is expected to spread to other nearby countries where the production of processing type vegetables such as broccoli, cauliflower is feasible.

Because of the EDB issue, a number of Latin American countries who are not participants in the CBI have voiced their concerns over the future of their tropical fruit exports to the United States. Brazil and Ecuador are among these. Brazil indicated that a ban on EDB may require that country to modify or even abandon its single newly constructed fumigation chamber installed only this past year in Sao Paulo. Lately, Brazil has been showing considerable interest in the U.S. market for papayas and mangoes.

II. ALTERNATIVES

A. The Research, Development, and Implementation Process

The development of a commercially viable quarantine treatment schedule is of necessity a lengthy process requiring effective communication and cooperation between scientists, regulatory officials, and industry. The illustration on Page 9 shows how this process evolves during the various stages of development from idea to commercial practice with three organizations: ARS, APHIS, and industry. Two keys to rapid regulatory approval of a given technology are (1) planning the experimental protocol to meet the demanding quarantine requirements and, (2) having ARS scientists work with APHIS inspectors and industrial workers during scale-up of the technology to commercial practice. If these three groups were to work in isolation, the approval time for an alternate technology would increase. The time frame for this process could take anywhere from 3 to 40 years.

TABLE 2

IMPORTED PRODUCTS FUMIGATED WITH EDB---FY 1982

Grapefruit	1,256,665 kg
Mangoes	34,280,135 kg
Oranges	11,374,022 kg
Papaya	240,647 kg
Tangerines	23,529,128 kg

Country of Origin

Grapefruit--
Mexico, Honduras, Dominican Republic

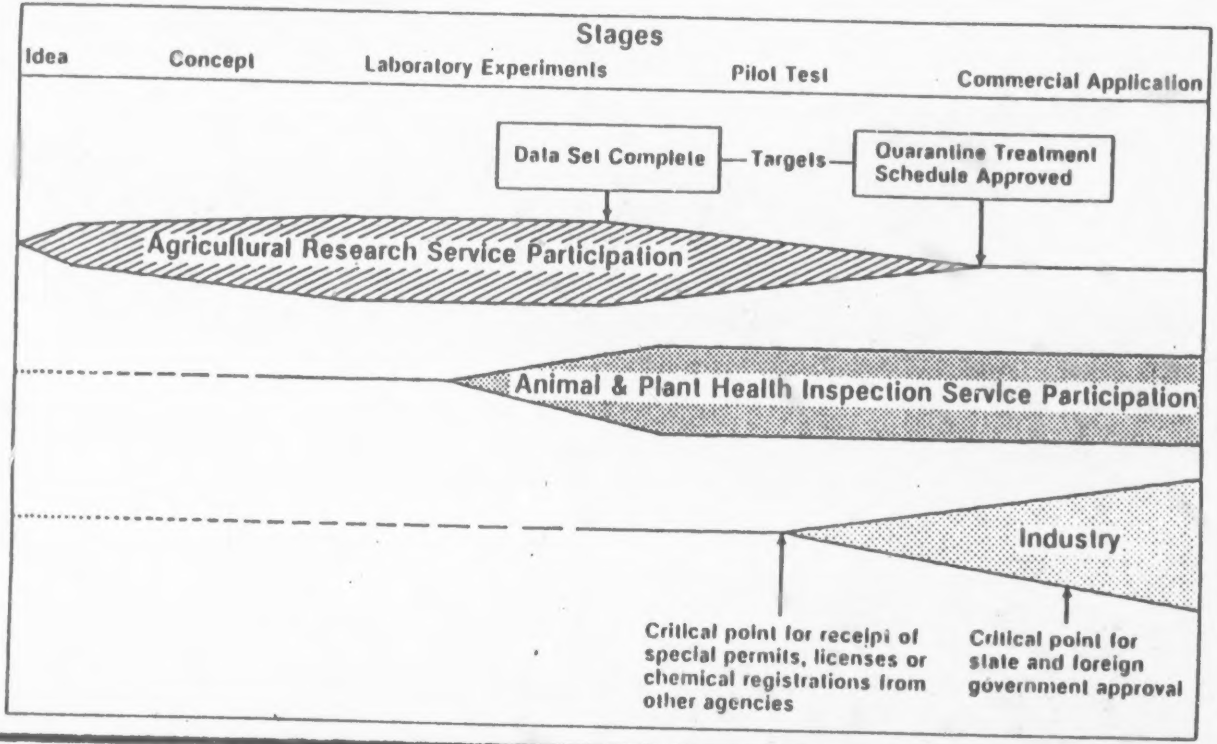
Mangoes--
Mexico, Jamaica, Haiti, Dominican Republic, Chile, Brazil

Oranges--
Mexico, Costa Rica, Spain

Papaya--
Guatemala, Bahamas, Dominican Republic, Colombia, Brazil

Tangerines,
Mexico, Spain, Morocco

The Process for Implementing a Quarantine Control Program



Stages
Idea
Concept
Laboratory Experiments
Pilot Test
Commercial Application
Data Set Complete
Targets
Quarantine Treatment Schedule Approved
Agricultural Research Service Participation
Animal & Plant Health Inspection Service Participation
Industry
Critical point for receipt of special permits, licenses or chemical registrations from other agencies
Critical point for state and foreign government approval

EDB is a broad spectrum fumigant for fruits and vegetables. The chemical can kill the five major fruit fly quarantine pests with little or no damage to commodities (phytotoxic effects), and the method of application fits within the marketing system currently used (truck, rail, air, and sea). No single method of quarantine treatment is known that can directly replace EDB fumigation for all its uses.

The Agricultural Research Service has conducted research for more than 40 years on control of fruit flies in the field, and in commodities after harvest. The expenditure of approximately $20 million in 1983 dollars has yielded developments such as sterile male fruit fly eradication methods, identification of insect lures, development of traps, evaluation of 3,000 chemicals for fruit fly control, and many basic studies on the biology of the pests and host commodities. The ARS 1984 fiscal year budget for fruit and vegetable quarantine treatments is $4,746,000 of which $1,589,000 is spent solely on EDB alternative technologies. The principal ARS research laboratories are located in Miami, Gainesville and Orlando, FL; Weslaco, TX; Fresno, CA; Yakima, WA; Hilo and Honolulu, HI. Basic research to develop new approaches to this problem and others is also conducted at a number of other ARS locations.

An active research program of post-harvest control of fruit flies is also conducted by the State universities and the Florida Department of Citrus. Research is coordinated through a Regional Project. The participating institutions and areas of work are shown in Reference 8.

The APHIS Plant Protection and Quarantine technical staff work closely with the research scientists during the later stages of technical development. Research protocols are jointly planned to assure that required data on insect mortality and fruit quality are obtained to develop a quarantine treatment schedule. APHIS takes into consideration special information needs of State and foreign governments during this planning so that approval as a quarantine treatment can be quickly obtained.

In all activities where Federal involvement occurs, the activity is a cooperative effort between the U.S. Department of Agriculture and the affected States. Quarantine boundaries, treatments, and certification procedures are mutually developed and implemented. Where foreign governments are involved, USDA serves as the liaison for the U.S. industry. At the request of the industry, USDA has discussed successfully with foreign countries, such as Japan, the use of possible alternative treatment procedures. Periodic program reviews and critiques are conducted involving all cooperators. When EPA initiated regulatory review of EDB, numerous meetings were held with the industry to explore alternatives and develop action plans that would result in alternative treatment procedures to EDB.

As mentioned in Section I. B. 2., two technical work groups involving Federal, State, and industry organizations have been established to develop and implement EDB alternatives for grapefruit and papayas. The action plan giving an overview of alternatives, priorities, and target dates is given in Table 3.

TABLE 3

Projected Milestones and Decision Points for Alternative Quarantine Treatment Schedules

Commodity/ Pest	Method	Responsible Agency	Milestone	Completion date (decision point)
Grapefruit/ Caribbean fruit fly	MB fumigation	ARS	Lab data [a]	4/1/84
		ARS	Confirming test [a]/[b]	5/1/84
		APHIS	Test on commercial load	6/15/84
		APHIS	Determine regulatory acceptability of schedule	6/15/84
	Phosphine fumigation	ARS	Lab data [a]	4/1/84
		ARS	Confirming test [a]/[b]	5/15/84
		APHIS	Test on commercial load	6/15/84
			Determine regulatory acceptability of schedule	6/15/84
Papaya/ trifly[c]	Stage of ripeness, + hot water immersion + cold temp.	ARS	Lab data[a]	complete
		ARS	Confirming test[a]/[b]	complete
		ARS/APHIS	test on commercial load	4/1/84
		APHIS	Determine regulatory acceptability of schedule	4/15/84
	Stage of ripeness, + two separate hot water immersion	ARS	Lab data [a]	3/15/84
		ARS/APHIS	Confirmatory test [a]/[b]	5/1/84
		APHIS	Determine regulatory acceptability of schedule	5/15/84
	Phosphine fumigation	ARS	Lab data [a]	4/1/84
		ARS/APHIS	Confirmatory test [a]/[b]	4/15/84
		APHIS	Determine regulatory acceptability of schedule	5/1/84

Note: For each method, the milestone will be evaluated at the completion date to determine if the next milestone should be pursued.

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[a] Efficacy, quality and/or residue.

[b] Large scale "static" test.

The following approaches have been or are being considered as alternatives for EDB:

a. Other chemical fumigation treatment including:
- o Methyl Bromide (MB)
- o Phosphine
- o Others

b. Non-chemical treatment including:
- o Temperature manipulation
- o Modified atmosphere
- o Gamma irradiation
- o Biological control of fruit flies
- o Host resistance to pests
- o Combinations of the above
- o Microwave irradiation (phytotoxic effects unacceptable)
- o Ultrasound (only kills organisms in outer 2mm of fruit)

c. Combinations of a. and b. above, such as:
- o MB with modified atmosphere
- o MB with temperature manipulation
- o Preconditioning fruit to reduce phytotoxic effects of MB

d. Non-conventional treatment including:
- o Eliminating need for quarantine treatment by eliminating the quarantine pest
    - oo Fly-free period
    - oo Biological and physical barriers prevent pest invasion
- o Mechanical removal of infested fruits
- o Selecting fruit at the time of harvest that repel pests because of naturally occurring chemicals
- o Combining in-field pest control, post-harvest storage, processing, and packaging that will eliminate infestation and provide security

Table 4 gives a summary of the most promising alternatives to EDB fumigation of grapefruit and papayas.

B. Near-Term Alternatives Available by January 1985.

1. Grapefruit

Grapefruit from Florida is under quarantine restrictions imposed by Arizona, Texas, California, and Japan because of the Caribbean fruit fly. Texas grapefruit is under Federal quarantine restrictions because of the Mexican fruit fly.

Florida is a major exporter of grapefruit to Japan. About 18 percent of Florida's fresh grapefruit production is shipped to that country annually. For the 1982-83 season, this totaled 293.5 million pounds. About 26 million pounds of fresh grapefruit are shipped annually from Florida to California. Up to 1983, EDB was the only acceptable quarantine treatment method available.

TABLE 4

Summary of Most Promising Alternatives to EDB Fumigation
(Ready for Adaptation by Industry by Jan. 1985)

Quarantine Restriction by Indicated Categories				Destination/Transportation System
Insect	State	Commodity	Alternative	
Caribbean fruit fly (all citrus)	Florida	Grapefruit (all citrus)	Cold treatment	Japan/Sea
			Methyl Bromide	CA, TX/Truck
			Phosphine	CA, TX/Truck
Mexican fruit fly	Texas	Grapefruit	Fly-free zones	All
Mediterranean fruit fly	Hawaii	Papaya	Fruit selection plus hot and cold treatments	CA/Sea
			Fruit selection plus 2 hot treatments	Japan, U.S./Air
			Phosphine	Japan, U.S./Air
Oriental fruit fly	Hawaii	Papaya	Fruit selection plus hot and cold treatments	CA/Sea
			Fruit selection plus 2 hot treatments	Japan, U.S./Air
			Phosphine	Japan, U.S./Air
Melon fly	Hawaii	Papaya	Fruit selection plus hot and cold treatments	CA/Sea
			Fruit selection plus 2 hot treatments	Japan,U.S./Air
			Phosphine	Japan, U.S./Air

Unless an alternative to EDB is found, about 18 percent of the fresh grapefruit shipped from Florida to Japan would have to be diverted to an alternative use. Normal grapefruit market conditions indicate this fruit would probably be diverted to processing with a decrease in on-tree price of about 3.4 cents per pound of fruit or loss of about 1.9 million dollars for the fruit diverted to other products. Table 5 gives a summary of the estimated cost comparison of EDB to various alternative scenarios.

a. Cold Treatment of the Caribbean Fruit Fly in Grapefruit

Grapefruit, a temperature sensitive fruit, can be preconditioned to withstand near freezing conditions by holding fruit at 60°F for 7 days. Caribbean fruit flies are killed if they are exposed to 34°F for 19 days. Therefore, the total time for quarantine cold treatment is at least 26 days. With temperatures, slightly higher than 34°F, fruit must be exposed to cold temperatures for slightly longer periods to provide quarantine security. The Japanese have accepted intransit cold treatment as a quarantine treatment method. This grapefruit marketing system fits with this alternative since sea shipping transit time is approximately 22 days. Industry is currently evaluating the commercial viability of this technique. Cold-treated fruit shipped last year arrived in good condition and quality was not impaired. The first shipment of the 1983-84 season showed significant fruit damage. It appears the damage may have been due to an unusually late-maturing crop, the effect of degreening, storage temperature after treatment and/or dehydration of fruit when storage humidity drops below 85%. Japanese warehouses are not equipped to maintain grapefruit at cold temperatures to avoid dehydration. Early season fruit picked at a later date arrived in Japan with no significant damage when compared with EDB treated fruit. If the technical problem encountered with the first shipment can be solved, use of cold treatment compared to EDB fumigation would result in treatment cost increases estimated at 25 to 40 cents per box. This represents a 1.7 to 2.72 million dollar increase in treatment costs which is 6 to almost 10 percent of the F.O.B. value of grapefruit shipped to Japan during the 1982-83 citrus season.

It is unlikely that a substantial quantity of cold-treated grapefruit would be shipped to California since the storage facilities for 26 days (7 days of preconditioning plus 19 days of treatment) at temperatures to meet quarantine requirements are not available at this time. Some shippers may be able to obtain cold treatment facilities. However, treatment costs for the California market are likely to increase by about $1.20 to $1.26 per box or 2.8 cents per pound assuming the increased demand for cold treatment facilities does not increase the price of storage.

b. Phosphine Fumigation for Caribbean Fruit Flies in Grapefruit

Phosphine, generated from aluminum or magnesium phosphide, is a slow-acting fumigant and requires considerably longer treatment time than the two-hour EDB fumigation. A treatment schedule using 33 grams of magnesium phosphide per 1,000 cu. ft., for three days at ambient temperature will provide quarantine security. Recent studies show no phytotoxic effects; however, some of the earlier studies did show some fruit damage. Preconditioning fruit and appropriate storage temperatures after treatment may be a means to consistently prevent potential injury due to phosphine. Recent data show damage to treated fruit held at 50°F and no damage when held at 60°F.

EDB treatment costs about 10 cents per box with 6 cents being the cost of treatment and 4 cents for extra handling. The current EDB fumigation chambers could be used with phosphine provided some modification is made to reduce the corrosive effects of the chemical. Phosphine treatment would cost 34 cents to 64 cents per box depending on the number of treatments per week. This would result in an increase of 24 to 54 cents per box above EDB costs. There could be a short-term shortage of treatment chamber space with the longer treatment time. Construction of substantial additional fumigation chamber space could result in increased costs beyond those estimated here.

c. Methyl Bromide (MB) Fumigation for Caribbean Fruit Flies in Grapefruit

MB may be a preferable fumigant as compared to phosphine because treatment time is in hours rather than days and current fumigation facilities can be used with minimal modification. Published data by the ARS, USDA Miami laboratory show that 2 1/2 lbs. per 1,000 cu. ft., at ambient temperatures for 2 hours, with 20% of the chamber volume occupied will provide quarantine security (current criteria is 99.9968% insect mortality or probit 9). In these recent experiments, no fruit injury or decay due to MB was noted. However, some injury/decay was recorded in earlier studies. Experiments are in progress to determine why injury was obtained in the past and to determine how to avoid MB injury. Promising results are being obtained. Commercial-scale evaluation will be implemented soon. Based on published ARS, USDA data, California has "temporarily" approved use of MB at the 2 1/2 lb./1,000 cu. ft. rate.

The estimated treatment cost of MB fumigation when compared to EDB would be 3 to 6 cents more per box due to the higher cost of MB. Toxicological evaluation on MB is continuing and this chemical can not be considered a permanent replacement for EDB.

d. Methyl Bromide for Mexican Fruit Flies in Grapefruit

The Texas citrus industry relies heavily on the fly-free zones concept discussed below. When the Mexfly is detected at a field population level that requires quarantine treatment, untreated fruit cannot be shipped to citrus growing areas. The only USDA approved quarantine treatment schedule is with EDB fumigation. Based on results to date with the Florida Caribbean fruit flies, MB may be the best alternative fumigation method if treatment is necessary. Research will be started at the ARS Mission, Texas laboratory within a few months to test this concept.

e. Quarantine Certification Based on Freedom From Infestation

In 1981, the citrus industry formed a technical advisory group that included USDA representation to review the available data on the dynamics of the Mexfly in the Rio Grande Valley of Texas. As a result of this evaluation, a protocol (see Reference 9) was developed that included increments of detection in conjunction with the release of sterile flies. Since the Mexfly population is at low levels during winter months in the Rio Grande Valley, it was proposed that if the early population could be detected and measured as it increases, and if the population could be managed by the release of sterile male insects, then perhaps it could be demonstrated that there is a period during which fruit could be moved with only a certification of freedom from infestation and no post-harvest quarantine treatment. This approach was studied during the 1981-82 citrus season wherein Mexfly traps correctly indicated populations and fruit infestation. Further refinements were made in the program for the 1982-83 season and fruit was shipped with only fly-free certification from October 15, 1982, until the first week in March 1983, when EDB fumigation was again required because of Mexfly population increases.

Further refinement of the protocol occurred during the 1983-84 season which allowed an increase in the number of trapped Mexflies in citrus groves before fumigation of grapefruit was started. Also, spraying pesticide on host vegetation was used in lieu of fumigation. Field treatments or fumigation was required in one-half the Rio Grande Valley by mid-November due to the large residual Mexfly populations from the preceding season.

Even though USDA has taken no regulatory action on the Caribbean fruit fly occurring in Florida, we are cooperating with the State and industry to develop a protocol in Florida similar to the one in Texas. Technology is not as advanced nor is much information available on the population dynamics of this fruit fly as compared to the Mexfly in Texas.

The December 1983 cold wave severly damaged citrus orchards in Texas and Northern Mexico and it is not known how soon full grapefruit production can again reach levels of previous years. The freeze has also reduced Mexfly populations to very low levels making it feasible to consider eradication of the insect from the Rio Grande Valley and Northern Mexico to a natural ecological barrier where Mexfly host vegetation is sparse. APHIS will complete construction of a fruit fly rearing and male sterilization facility in Mission, Texas in 1984. When further information is collected on the number of Mexflies now remaining in this geographical area, a decision will be made on the feasibility of eradication of the insect. The extent of the area to be covered will be based on cost and the cooperation of the Mexican Government.

Until fruit flies can be eradicated from an area, it is necessary to maintain a backup post-harvest fruit quarantine treatment. The costs of eradication and prevention of pest reentry are extremely high though technically feasible. Recent scientific discoveries show promise in quickly identifying infested fruit (current inspection employs cutting open a representative sample of fruit) discussed on Page 22.

f. Emergency Response Needs

EDB fumigation is needed for emergency control of tropical fruit fly pests in the event of accidental introductions. The ability to use the fumigant on short notice provides a way to keep supplies of food available while protecting agriculture from further spread of pests. Without such an emergency procedure it would be necessary to embargo and destroy host products, an act that may cause significant disruptions to our nation's food supply. It was estimated that preharvest and post-harvest costs for 20 selected crops for the first year of a total California quarantine would range from $817 million to $1,256 million in 1981 dollars.

2. Papaya

The papaya industry in Hawaii shipped about 34 million pounds of fresh papaya to Japan and the 48 contiguous States during the 1982-83 season. These shipments represented about 87 percent of papaya production in Hawaii, which had a farm value of $11 million. About 17 percent of these shipments went to Japan. All papaya shipped to Japan or the 48 contiguous States were treated with EDB under quarantine restrictions to prevent spread of 3 species of fruit flies.

TABLE 5

Cost of EDB and potential alternative scenarios for use on Florida grapefruit

Treatment	Percent of fruit treated a/	Market Destination	Treatment cost per box b/	Total treatment cost	Increased treatment cost
			Dollars	Million dollars	
EDB	100	All	0.10	31.98	--
Alternative scenarios c/					
1. Cold Treatment	75 25	Japan CA, TX, AZ	0.35 to 0.50 1.30 to 1.36	83.94 to 119.91 103.92 to 108.72	
Scenario Total	100		--	187.86 to 228.63	155.88 to 196.65
2. Cold Treatment Methyl Bromide	75 25	Japan CA, TX, AZ	0.35 to 0.50 0.13 to 0.16	83.94 to 119.91 10.39 to 12.79	
Scenario Total	100		--	94.33 to 132.70	62.35 to 100.72
3. Cold Treatment Phosphine	75 25	Japan CA, TX, AZ	0.35 to 0.50 0.34 to 0.64	83.94 to 119.91 27.18 to 51.16	
Scenario Total	100		--	111.12 to 171.02	79.14 to 139.09
4. Irradiation	100	All	0.29 to 0.526	92.73 to 168.20	60.75 to 136.22

a/ Assumes a 42.5 pound box.

b/ Percent treated with scenarios 1, 2, and 3, based on expected problems with cold treatment.

c/ Scenarios 1, 2, and 3, were developed assuming the alternative chemicals would be used only where cold treatment was not practical. Methyl bromide could become a widespread replacement for EDB if its use becomes practical with increased treatment costs of 9.6 to 19.2 million dollars.

NOTE: Costs are estimates only. For some treatments estimates may be less reliable since no comparative experience base exists to develop estimates.

a. Combination of Hot Water Dip, Cold Treatment, and Degree of Ripeness

Three species of fruit flies attack payapas in Hawaii; the oriental fruit fly, Mediterranean fruit fly, and melon fly. The predominant species is the oriental fruit fly. It is known that the three species cannot survive if the fruit is less than a quarter of full ripeness. The presence of benzyl isothiocyanate (BITC) in the latex and tissues (1) repels egg-laying females significantly, and (2) kills eggs and hatched larvae if the concentration remains above 52.6 ppm. The concentration of BITC when papaya is mature green or "color turning" is well above the 52.6 ppm level. If quarter ripe papaya were held at 73.4°F, the fruit will rapidly mature and the BITC concentration will rapidly drop to below the insect control level, e.g., at 24 hours after harvest, BITC concentration drops to 26 ppm.

Until a rapid, accurate mechanical system to determine ripeness is available, a visual, subjective selection by workers must be used. However, to achieve quarantine security, heat treatment (120°F for 20 minutes) plus cold (47°F for 10 days) of visually selected papayas will maintain quality. This cold treatment period is a viable alternative for intransit sea shipments to California. Usual commercial processing of papaya employs a 120°F, 20 minute heat-treatment to prevent spread of decay causing organisms. Commercial scale evaluation of the hot/cold treatment is in progress to determine if the results will be similar to laboratory and simulated shipment tests. Estimated treatment costs indicate this process will be less expensive than current EDB fumigation. There is some question regarding possible additional cost of harvesting fruit at less than quarter ripe. Actual experience is needed to determine whether increased harvest costs would be incurred.

b. Combination of Two Hot Treatments and Degree of Ripeness

Exposing less than quarter ripe papayas to two separate hot water treatments may be another method to insure insect quarantine security. Research indicates that exposing these fruit to water temperatures of 108°F for 40 minutes followed by an exposure to 120°F for 20 minutes gives adequate quarantine protection for all three fruit flies. This procedure shows promise for the air freight markets of Japan and the eastern U.S. However, large scale commercial tests should be conducted and regulatory approval must be received before it is accepted.

c. Phosphine Fumigation

Laboratory data show that theoretically a one-day treatment with phosphine from magnesium phosphide should provide quarantine security and not injure the fruit. Tests are planned in ARS's

Hilo, Hawaii laboratory in 2 months to evaluate its commercial feasibility. Phosphine may become the viable alternative until a reliable method of harvesting fruit quarter ripe or less is developed. If the one-day fumigation works, it may be more practical for industry to utilize one reliable treatment method than the combinations mentioned in a. and b. above.

Table 6 presents cost comparison scenarios between EDB quarantine fumigation, the alternative treatments and shipment methods.

C. Long Term Alternatives

1. Gamma Irradiation

Use of radiation techniques such as microwaves and ultra high frequencies have been investigated. Of these, gamma irradiation shows the most promise. All insects can be killed with gamma irradiation. However, in many instances, the killing dosage will injure the commodity. For those commodities currently dependent on EDB, research shows that use of gamma irradiation is technologically feasible especially for fruit flies in papaya and grapefruit. To permit use of low dosage of irradiation, research is in progress to show that it is not necessary to kill all insects present for quarantine security purposes. At very low dosages (less than 10 kilorads) few insects would survive, and of those survivors, none will be able to produce progeny. Many commodities currently injured at dosages necessary to kill fruit flies will not be injured if the criterium for quarantine security is changed from "mortality" to the "inability to produce progeny". Such a change in definition will require prior consultation and approval by USDA, States and foreign countries.

At the present time gamma irradiation has been approved by the U.S. Government for disinfestation of grain, antisprouting of potatoes and disinfestation of spices; however, only disinfestation treatment of spices is used commercially. A special review by three United Nation organizations (World Health Organization, Food and Agricultural Organization, and International Atomic Energy Agency) found no toxic risk to humans for food exposed up to 1,000 kilorads irradiation. The U.S. Department of Health and Human Services is currently developing regulatory guidelines for processing all foods with up to 100 kilorads dosage. It is hoped that a proposed rule will soon be published in the Federal Register; however, considering the time period needed to receive public comment, to make further modification and to publish a final rule, it is not expected that approval for food treatment can be available until later this year. There are some questions regarding consumer acceptance of irradiated food products. Assuming these questions can be resolved, firms experienced with irradiating medical equipment have expressed interest in irradiating food. Assuming FDA approval were granted for food irradiation, irradiators could be operational about 18 months after all necessary local permits and licenses are obtained. Therefore, irradiation cannot be available as an alternative to EDB fumigation by the proposed cancellation date of September 1, 1984. A more realistic date for its full scale commercial use as a quarantine treatment of fruits and vegetables may be 1986.

TABLE 6

Cost of EDB quarantine fumigation and potential alternative scenario for use on papaya

Treatment	Total fruit treated	Shipment Method	Treatment cost per pound	Total treatment cost	Increased treatment cost
			Cents		Million dollars
EDB d/	100	All	0.15	5.1	--
Alternative Scenarios					
1. Heat/Heat b/	70 a/	Air	0.15 to 0.20	3.57 to 4.76	
Heat/Cold b/	30	Sea	(0.15)c/	(1.53)	
Scenario Total					(3.06) to (1.87)b/
2. Phosphine	100	All	0.375 to 0.75	12.75 to 25.5	7.69 to 20.4
3. Irradiation	100	All	0.435 to 0.789	14.79 to 26.83	9.69 to 21.73

a/ Distribution based on portion which is surface shipped and could be heat/cold treated.

b/ The feasibility of this option is based on the assumption that fruit can be harvested at 1/4 ripe to meet quarantine standards. APHIS, USDA has not approved any detection method.

c/ This represents a cost decrease since the fruit is surface shipped under refrigeration with EDB treatment and current practice is not to impose an additional charge for shipment under controlled temperatures.

d/ Current practices to heat dip all papaya for 20 minutes at 49°C which would be utilized with all alternatives. In addition, this heat dip is the first heat dip of scenario 1.

NOTE: Costs are estimates only. For some treatments estimates may be less reliable since no comparative experience base exists to develop estimates.

Various cost projections have been developed which indicate gamma irradiation would cost about 0.18 to 0.24 cents per pound (7.8 to 10.1 cents per box of grapefruit) plus the cost of transporting fruit to the plant and unloading and loading the conveyance carrying the fruit. If irradiation plants could be located adjoining the ship loading facilities for grapefruit exports to Japan, much of the extra handling cost could be avoided. This would require altering either the scale of irradiation plants or the location of shipping facilities which would significantly increase the unit cost of processing fruit. Assuming irradiation plants were at locations near the current EDB fumigation chambers, handling costs would range from 21.2 to 42.5 cents per box. This would give a total cost for grapefruit treatment of 29 to 52.6 cents per box as compared to 10 cents per box for EDB (see Table 5)

Fruit being exported from Hawaii would face additional logistical problems of moving all fruit produced on several islands to a control irradiator for treatment. It is estimated that irradiation plus handling would cost 0.479 to 0.789 cents per pound compared to 0.15 cents per pound with EDB (see Table 6). There remain numerous questions regarding the costs of handling fruit to be irradiated and the size of the processing plants which are yet to be constructed. Therefore, realistic cost estimates are not possible until an actual facility is operational which can handle the volume ands value of fruit and vegetables produced.

2. Detection of Fruit Fly Infested Fruit

A device has been discovered that will detect all stages of fruit fly larvae in the host commodity. It is based on the use of an accelerometer, which is a transducer that will detect vibrations in solids. Currently all stages of the Caribbean fruit fly larvae can be detected, except early and mid-first instar larvae. The research effort currently is to improve the sensitivity of the accelerometer so that newly hatched larvae can be detected. This will then be used to detect fruit infested with larvae so that they may be removed. An effective quarantine treatment schedule can then be developed by combining larval removal with a method that will kill or eliminate insect eggs.

III. Establishment of Priorities

The Agricultural Research Service and the Animal Plant and Health Inspection Service have established immediate priorities in view of the Environmental Protection Agency's indication on February 3, 1984, to make a decision in a few weeks on EDB fumigation of fruits and vegetables. An accelerated research program and quarantine review schedule was discussed for papaya, citrus, and mango alternatives in view of EPA's decision to take action earlier than September 1, 1984, as previously announced. Four areas were assigned highest priority based upon industry and foreign government indications of potential disruption of fruit and vegetable markets. These are: 1) acceleration of work on papaya alternatives to have an approved treatment ahead of the timeframes indicated on Page 11, Table 3; 2) speed up work on methyl bromide fumigation of grapefruit; 3) concurrent with the grapefruit activities, test methyl bromide fumigation on oranges and tangerines, which has not proven acceptable in the past; 4) initiate research on temperature treatment on mangoes for fruit fly control.

USDA in cooperation with other Federal Departments, and the private sector, will continue its accelerated research program in order to alleviate undue economic harm to the American farmer and to maintain our vital international agricultural trade relations.

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